IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION (at Cincinnati)

TARA BROWN 10702 Pinedale Drive, Apt. #1 Louisville, KY 40299 **Plaintiff,** v. **ABUBAKAR ATIQ DURRANI, M.D.,** Serve: Orthopedic & Spine Institute 203 Canal Road Lahore 54000 Pakistan (Serve by regular mail) and **CENTER FOR ADVANCED SPINE TECHNOLOGIES, INC.** Serve: Orthopedic & Spine Institute 203 Canal Road Lahore 54000 Pakistan (Serve by regular mail) **Defendants.**	: :	**Case No. _____** **Judge _____** **COMPLAINT FOR DAMAGES WITH JURY DEMAND ENDORSED HEREON**

Plaintiff, Tara Brown, for her *Complaint for Damages with Jury Trial Demand Endorsed Hereon* (the "Complaint) against defendants Abubakar Atiq Durrani, M.D. and Center for Advanced Spine Technologies, Inc., (together, the "defendants"), states and alleges as follows:

I. PARTIES.

1. The incidents giving rise to this action and the subject matter of the Complaint arise out of medical treatment, fraud, acts and omissions, and conduct that occurred in Hamilton County, Ohio.

2. At all times relevant, Plaintiff was a resident of and domiciled in the State of Kentucky.
3. At all times relevant, Dr. Abubakar Atiq Durrani (hereinafter "Dr. Durrani") was licensed to and did in fact practice medicine in the State of Ohio.
4. At all times relevant, Center for Advanced Spine Technologies, Inc. (hereinafter "CAST"), was licensed to and did in fact perform medical services in the State of Ohio and was and is a corporation authorized to transact business in the State of Ohio and Kentucky.

II. JURISDICTION AND VENUE.

5. The amount in controversy exceeds the jurisdictional threshold of this Court.
6. This Court is thus the proper venue to grant Plaintiff the relief sought.
7. This Court has jurisdiction based upon diversity under 28 U.S.C. § 1332.

III. FACTS.

8. Tara Brown, 29-year-old female, was referred to Dr. Durrani for complaints of neck pain and numbness in her left hand, especially in her middle and third and fourth fingers. Tara Brown's medical history included Ehler's Danlos syndrome (EDS), Hyper Adrenergic Pots (Postural orthostatic tachycardia syndrome), rheumatoid arthritis(RA), Mitral valve prolapsed (MVP), Dilated aorta, and renal stones, with a surgical history of an Appendectomy, Cholecystectomy, Hysterectomy, Tonsillectomy, and Cystocele/rectocele repair.
9. At the first office visit at CAST dated 01/06/2009, Dr. Durrani ordered a complete MRI, chiropractic massage, and physical therapy for the neck pain.
10. At the CAST visit dated 05/07/2009, Dr. Durrani recommended she stop the chiropractic manipulation and use a cervical collar. He would see her back in 6 months.

11. Around two years later, Dr. Durrani, at the CAST visit dated 07/19/2011, examined Tara and ordered an MRI of the cervical spine in flexion and extension, and a CT study. Dr. Durrani wanted to evaluate C1 and C2 and rotatory gland.
12. Dr. Durrani reported he is very concerned because Tara Brown has every sign of a very significant cervical instability and ordered diagnostics.
13. On 08/02/2011, ProScan Imaging CT of the cervical spine w/o contrast, showed vertebral bodies normal height, craniocervical junction appears normal. The atlantodens interval is normal. The dens remain centered in rotation. C1-C2 rotations is symmetric.
14. At CAST, 08/09/2011, Dr. Durrani intentionally misinterpreted the results of the rotational CT scan, and falsely informed Tara Brown she has an 80-85% uncoverage of C1-C2 when she looks left to right, which is very significant and convinces Tara she requires a C1-C2 spinal fusion. Dr. Durrani places Tara in a cervical collar and schedules the surgery.
15. It is later learned NO spine doctor in the country would ever do this C1-C2 surgery on an EDS patient. Dr. Durrani has performed it on about 30 Deters Law Plaintiffs.
16. It is common for Dr. Durrani to prey upon disabled patients due to ease of insurance payment for surgeries.
17. Dr. Durrani becomes the #2 Medicare and Medicaid provider in Ohio for Orthopaedic surgeons.
18. Dr. Durrani's interpretation of the diagnostics is exaggerated and contraindicates that of the radiologist. The radiologist reports a normal cervical spine with no instability. This is a common practice of Dr. Durrani to meet surgical requirements for spine surgeries.
19. Dr. Durrani performed an unnecessary surgery on Tara Brown at WCH on 10/05/2011.

20. Dr. Durrani dictated in the WCH operative report, that the arch of C1 was so thinned out that while drilling a pilot hole for C1 screw, he noticed a fracture. All prior diagnostics preoperatively report no fractures. Dr. Durrani tried to cover the damage by reporting it was found not inflicted by himself. Dr. Durrani dictated it was decided to not put the C1 screw on the left side. Dr. Durrani reported continuing his dissection down into the arch of C1 and implanted a 3.5mm screw measuring 26mm. Dr. Durrani noted implanting a 24 mm screw measuring 27mm measuring 3.5mm. A small rod was implanted using set screws.
21. Dr. Durrani performed a high-risk surgery which was contraindicated due to Tara Brown's comorbid conditions.
22. Dr. Durrani failed to order a DEXA scan preoperatively. DEXA scans are ordered to assess low bone density, common trait of EDS.
23. Due to Tara Brown's medical condition, she suffered a C1 fracture during the unnecessary surgery. Individuals with Ehlers Danlos syndrome (EDS), experience signs and symptoms include joint hypermobility, multiple joint dislocations, translucent skin, poor wound healing, easy bruising, hyper extensible skin, and unusual scars; and in any individual who experiences spontaneous rupture of an organ or dissection of a blood vessel. Joint dislocations or subluxations are common in most forms of EDS, and joint pain and premature degenerative arthritis are often consequences of the disorder. EDS patients require a team of doctors and Dr. Durrani failed to include other medical experts.
24. Dr. Durrani placed Tara at a great risk for bleeding and vascular rupture. Vascular fragility is common in EDS, and often needs cross matched prior to surgery. Staples are

used instead of stitches. Anesthesia can be hazardous with EDS, due to muscle weakness and neurological defects.

25. Individuals with EDS need low-resistance exercise to help increase muscle tone and stabilize loose joints. Physical therapy performed by a therapist who is experienced in working with patients with connective-tissue and joint dysfunction can be very helpful in the management of long-term health. Dr. Durrani did not prescribe this.

26. Dr. Durrani neglected to treat Tara Brown, with six consecutive months of physical therapy prior to recommending surgery. Treatment should have focused on physical therapy, medications, self-management, healthcare management team, and coping with EDS. The standard of care for individuals with EDS recommends noninvasive care unless the surgery is only option and completely necessary. This was not the case with Tara.

27. During the unnecessary risky surgery, Dr. Durrani implanted Medtronic's Infuse Bone Graft into Tara Brown's cervical spine which was contraindicated and without informed consent. According to the FDA and Medtronic Guidelines, Infuse Bone Graft is contraindicated in the cervical spine. Infuse Bone graft implanted into the cervical spine can cause serious side effects such as, compromise of airway due to edema, severe enough to need urgent treatment can occur within the first week of surgery. Off-label use of the Medtronic Infuse during cervical fusion surgery, or neck surgery, has been linked to a number of serious respiratory problems, nerve injuries and deaths. Medtronic provided sales representatives in the operating room during such neck surgeries to provide instruction and assistance to physicians. This is against hospital policy. Dr. Durrani failed to inform Tara of the serious side effects and his decision to implant Infuse off-label prior to surgery. Infuse Bone Grafts are risky, and can come with dangerous side

effects, including infection, ectopic bone growth, male sterility, bone and nerve injury, osteomyelitis, and urinary problems and increased cancer risk. These side effects are reported as implanted using the guidelines.

28. Dr. Durrani exaggerated and misinterpreted Tara Brown's diagnostics reports to meet surgical requirements to perform a high risk C1-C2 surgery on Tara Brown.

29. Dr. Durrani misdiagnosed and misinterpreted Tara Brown's diagnostics and reports C1-C2 instability. Dr. Durrani uses the words very significant to describe her articulation. That is a lie.

30. WCH's operative report includes spondylolisthesis as a diagnosis. Tara Brown was never diagnosed by Dr. Durrani or any other medical professional with spondylolisthesis. This is common practice of Dr. Durrani and WCH because insurance regularly approved spondylolisthesis.

31. The CAST consent dated 09/20/2011 lists C1-2 fusion. No off-label or contraindicated use of Infuse Bone Graft is listed on the consent. It is standard of care to inform the patient of all the details of off label use of BMP-2.

32. The WCH consent dated 10/05/2011 lists the surgeon as A. Durrani and the procedure as cervical 1-2 fusion. It neglects to inform of off-label and contraindicated use of Infuse Bone Graft

33. Dr. Durrani implanted Medtronic Infuse Bone Graft off-label during an unnecessary and with without consent at WCH 10/05/2011.

34. Tara Brown's WCH medical records do not report any cages implanted during the surgery. A proper cage is required to avoid ectopic bone growth.

35. Dr. Durrani implanted Medtronic Infuse Bone Graft into Tara Brown's cervical spine off-label and neglected the Black Box warning to never implant infuse into the cervical spine. Side effects such as, compromise of airway due to edema severe enough to need urgent treatment can occur within the first of surgery. Other side effects include, breathing issues, dysphagia (difficulty swallowing), dysarthria (difficulty speaking), coma, radiculitis, and/or need for hospitalization feeding tubes and tracheotomies and for additional surgeries. Off-label use of the Medtronic Infuse during cervical fusion surgery, or neck surgery, has been linked to a number of serious respiratory problems, nerve injuries and deaths. It also increases the risk of cancer. Infuse Bone Graft is not approved for use with EDS or patients with autoimmune disorders. Any patient receiving Infuse Bone Graft should have at least six months of non-operative treatment prior to implanting according to the guidelines. Dr. Durrani neglected to treat with non-surgical therapy.
36. Infuse is intended for a single level anterior lumbar interbody fusion single performed with all three components in a specific spinal region. The three components that the infuse device consists of are. A metallic spinal fusion cage (The LT cage). The bone graft substitute which consists of liquid rhBMP-2. And a spongy carrier or scaffold for the protein that resides in the fusion cage. swallowing, as well as decreased mobility from the over growth of BMP in the cervical spine.
37. Dr. Durrani did not use the indicated LT cage in the procedure. No cage was used in the clients' procedure. Making Dr. Durrani's use of BMP in this procedure off-label. The off-label use of BMP without the expressed or written consent and or knowledge of the client

is a violation of standards of care, as well as a violation of the manner in which BMP could be used in accordance with the FDA.

38. After Dr. Durrani, Tara Brown treated with Specialist in Genetics, Dr. Bradley Tinkle with Cincinnati Children's Hospital.

39. Tara now suffers from decreased range of motion and inability to turn her head. She relies on canes and walkers to assist with walking and keeping her balance. For long distances, Tara requires a wheelchair and has chronic and acute, unbearable pain.

40. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of cancer from Medtronic's own study. As a result, Plaintiff has an increased fear of cancer.

41. Plaintiff had office visits for post-operative care at Dr. Durrani's CAST office and treated far past the surgery date.

42. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

43. As a direct and proximate result of this surgery and Dr. Durrani's negligence, the Plaintiff has suffered harm.

44. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel informed Plaintiff of Dr. Durrani's propensity to use BMP-2 and legal counsel reviewed her intraoperative report and billing records.

MORE SPECIFIC ALLEGATIONS BASED UPON DISCOVERY AND DEPOSITION TESTIMONY

45. Krissy Probst was Dr. Durrani's professional and personal assistant handling professional, academic, travel, surgery scheduling, his journals, his Boards, his credentialing, his personal affairs and his bills.
46. Krissy Probst worked as Dr. Durrani's assistant for three years at Children's Hospital from 2006, 2007, and 2008.
47. Krissy Probst reported Dr. Durrani to Sandy Singleton, the Business Director at Children's for his having an affair with Jamie Moor, his physician assistant.
48. Krissy Probst resigned in 2008 from Dr. Durrani and remained working for three other surgeons in the Orthopedic Department.
49. Krissy Probst worked in the Orthopedic Department for eleven years from 2002-2013. She retired in May 2013.
50. Krissy Probst confirmed Dr. Durrani claims being a Prince, when he is not.
51. According to Krissy Probst, Dr. Crawford, an icon in pediatric orthopedics treated Dr. Durrani "like a son."
52. According to Krissy Probst, Dr. Crawford, Chief of Orthopedics at Children's unconditionally supported Dr. Durrani no matter the issues and problems Dr. Durrani faced.
53. Dr. Durrani's patient care at Children's Hospital dropped off considerably after Jamie Moor became his physician assistant and they began their affair.
54. Dr. Durrani was the only orthopedic spine surgeon at Children's who would perform a dangerous high volume of surgeries.

55. At Children's, Dr. Durrani would begin a surgery, leave and have fellows and residents complete a surgery or do the full surgery while he was in his office with Jamie Moor, his physician assistant for four or five hours.

56. Children's Board and administration knew about Dr. Durrani doing too many surgeries and not properly doing the surgeries. They did nothing.

57. Dr. Durrani argued to Children's administration when they complained to him that he made them money, so Children's tolerated him and allowed him to do what he wanted.

58. Dr. Durrani, when told by Children's that Jamie Moor had to leave, told Children's that he would leave too.

59. Dr. Agabagi would do one spine patient a day at Children's because it takes normally eight hours for a full fusion.

60. Dr. Durrani would schedule two to three spine surgeries a day at Children's.

61. Dr. Durrani would repeatedly have the Business Director, Sandy Singleton, or OR Director allow him to add surgeries claiming they were emergencies when they were not.

62. Dr. Durrani would leave a spine surgery patient for four or five hours in the surgery suite under the care of fellows or residents, unsupervised and sit in his office and check on the surgery as he pleased.

63. Dr. Peter Stern did not like Dr. Durrani while Dr. Durrani was at Children's because he knew all about his patient safety risk issues. Yet, Dr. Stern supported, aided and abetted Dr. Durrani's arrival at West Chester. It defies comprehension but was for one of the world's oldest motives—greed of money.

64. There is also a Dr. Peter Sturm, an orthopedic at Children's who also had no use for Dr. Durrani.

65. Dr. Durrani chose his own codes for Children's billing which he manipulated with the full knowledge of Children's Board and management.
66. Dr. Durrani was dating and living with Beth Garrett, a nursing school drop-out, with the full knowledge of his wife Shazia.
67. Dr. Durrani was close with David Rattigan until David Rattigan pursued Jamie Moor and Dr. Durrani would not allow David Rattigan in the OR at Children's for a long time.
68. Dr. Durrani, while claiming to have riches, does not. Dr. Durrani's wife's family paid for Dr. Durrani's education and it is her family with the significant wealth.
69. Medtronics paid for Dr. Durrani's trips and paid him $10,000 fees for speaking or simply showing up at a spine conference.
70. Krissy Probst's business director told her to save all Dr. Durrani related documents and information and she did.
71. While doing research at Children's, Dr. Durrani would misstate facts regarding his research. Children's knew he did this.
72. Dr. Durrani ended on such bad terms with Children's Hospital he was not allowed on the premises after his departure in December 2008, yet he performed a spine surgery there in February 2009.
73. Eric J. Wall, MD was the Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.
74. Sandy Singleton, MBA was the Senior Business Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

75. On information and belief, Dr. Durrani used his relationships with Children's officials to purge his Children's file of all patient safety and legal issues which had occurred as part of his departure "deal" which Defendants hide with privilege.

76. Defendants committed fraud by misrepresenting Dr. Durrani's reputation. Defendant knew he was doing unnecessary spine surgeries and concealing them from Plaintiffs. With the intent to mislead Plaintiffs and knowing Plaintiffs would rely upon the misrepresentations and concealment, Defendant caused harm to Plaintiffs. Defendant knew their false information regarding Dr. Durrani was material to Plaintiffs decision making in choosing Dr. Durrani as a surgeon, allowing him to perform surgery, following his recommendation and being trusting to have their procedures at Defendant hospitals.

77. Dr. Durrani's CAST website states in part: "The entire focus at CAST is on the patient. From the ease in getting in to see a physician…to wellness, therapy and treatment programs that can help patients avoid surgery…to minimally invasive techniques if surgery is necessary…to our remarkable facility and one-site convenience. It's time patients have the level of preventive care and advanced treatment we offer. Atiq Durrani, MD- Founder of CAST." As shown and will be shown, this is a material misrepresentation which is false relied upon by Dr. Durrani's patients including Plaintiffs to allow Dr. Durrani to perform unnecessary surgeries on Plaintiffs.

78. Gerry Goodman worked under a Corporate Integrity Agreement in 2010 at West Chester/UC Health.

79. Gerry Goodman, from August to November 2010, while serving as the interim director of OR nursing at West Chester Medical Center, complained to administration including

Mitch McCrate about Dr. Durrani's deviations and violations of law, policies, bylaws, rules and regulations which were affecting patient care, including Plaintiffs.

80. Mitch McCrate told Gerry Goodman West Chester/UC Health wasn't concerned because "the hospital had state funding and therefore was not held to qui tam rules."

81. Gerry Goodman told Mitch McCrate, General Counsel; Jack Talbot, HR; George Caralis, COO and Kevin Joseph, MD, President; that Dr. Durrani had a "partner" who had not received provider status and Dr. Durrani was billing his "partner" under Dr. Durrani's provider number, something which was illegal.

82. The "partner" was Dr. Shanti.

83. Dr. Durrani and Dr. Shanti would do three or four cases simultaneously and bill them simultaneously.

84. Gerry Goodman told McCrate, Talbot, Caralis and Joseph she could not work in a place which condones illegal practices. They asked her to ignore them. She refused.

85. Dr. Durrani, according to Gerry Goodman, did whatever he wanted in the OR and knew he could get away with it including being treated like a king by the vendors.

86. Vendors such as Medtronic representatives were allowed in the OR after going through the preapproved process they must go through. David Rattigan, Dr. Durrani's primary vendor, worked at Bahler peddling Medtronic products.

87. Dr. Durrani was abusive to his and West Chester/UC Health staff. This was tolerated by West Chester/UC Health and affected patient care including that of Plaintiffs.

88. Dr. Durrani never cared about other schedules or the West Chester/UC Health OR schedule.

89. Dr. Durrani declared every surgery an emergency to ignore schedules.

90. Dr. Durrani received two full days and two half days of block time at West Chester/UC Health. It was never enough time for his over utilization.

91. When Gerry Goodman would say no to a Dr. Durrani scheduling request, Dr. Durrani would contact West Chester/UC Health administration and she would be overridden.

92. Gerry Goodman had skill, knowledge and experience to recognize a "Dr. Durrani" because she had been involved in the outing of another over-utilizer and unnecessary procedure surgeon performing cardiac catherizations.

93. Spine surgeons usually do one or two a day, possibly three surgeries a day if an emergency.

94. Dr. Durrani would often do four, five and even six surgeries.

95. Dr. Durrani and Dr. Shanti would walk from surgical room to surgical room with all the spine patients "open" for an extended time past the standards of care.

96. On at least two occasions, Dr. Durrani patients were open for in excess of an hour waiting for him to come into the case.

97. When Gerry Goodman would complain to Dr. Durrani about patients being under anesthesia and the operative site open for long periods of time, Dr. Durrani would claim "we are covering anesthesia with antibiotics."

98. When Dr. Durrani performed with Dr. Shanti these multiple simultaneous procedures, they were billed as if he was the attending surgeon in all three surgeries.

99. The Dr. Shanti and Dr. Durrani "open and switch" to do the surgery, we have labeled the "Shanti Shuffle."

100. The Shanti Shuffle is not the normal. Shanti did not assist, he replaced.

101. Gerry Goodman complained to risk management repeatedly to no avail of the Shanti Shuffle.

102. When Gerry Goodman pointed out to risk management, Jill Stegman and David Schwallie that Dr. Durrani had all the "red flags" from over utilization and being bounced out of other area hospitals, they responded "how did you know." Gerry Goodman knew because anyone in hospital administration and management in the tristate in 2008 to 2013 knew. Dr. Durrani was no secret.

103. Jill Stegman and David Schwallie admitted to Gerry Goodman they knew about Dr. Durrani's over utilization, being "bounced out" of other hospitals and all the issues going on with him with the OR, but West Chester needed Dr. Durrani's numbers.

104. When Gerry Goodman complained to George Caralis about Dr. Durrani, he told Gerry Goodman to "keep your mouth shut and go back to work because you are just an interim."

105. George Caralis told Gerry Goodman that West Chester/UC Health needed Dr. Durrani surgeries and admissions and therefore they were not going to stop him.

106. Jill Stegman and David Schwallie informed Gerry Goodman they would get back with her about Dr. Durrani in a few days. They never did.

107. After Gerry Goodman was blown off by David Schwallie and Jill Stegman, she decided to leave her work assignment at West Chester/UC Health.

108. Gerry Goodman checked the written consents of BMP-2 patients including Plaintiffs which Dr. Durrani, CAST and West Chester/UC Health had them sign and confirmed they did not provide consent to BMP-2.

109. Gerry Goodman reported on the lack of consent for BMP-2 also to Schwallie, Stegman, Joseph, Caralis, Talbot and McCrate and they ignored her.

110. Gerry Goodman verified there was nothing in the patients' charts, including Plaintiffs' charts, reflecting they were informed of the risks of off label use of BMP-2.

111. Upon hearing her repeated complaints about Dr. Durrani, George Caralis told Gerry Goodman she was just an "emotional female."

112. Gerry Goodman reported to no avail patient safety issues caused by the OR staff working from 7 AM to midnight on Dr. Durrani patients. Fatigue caused deviations in standard of care by West Chester/UC Health staff's including in Plaintiffs.

113. No action was taken by West Chester/UC Health's board or management to correct the informed consent issue on BMP-2. The time period of Gerry Goodman's warning and complaints were fall 2010. Plaintiffs' claims arise from January 1, 2009 through May 2013. At least, according to Gerry Goodman's interim service, any Plaintiff having BMP-2 placed after the fall of 2010 at West Chester/UC Health is a further tragedy because the Board, administration and management can't obey notice and they allowed Dr. Durrani to continue placing BMP-2 at will. Why? Money. Despite having full knowledge of the issue, West Chester/UC Health's board and management allowed patients including Plaintiffs to have BMP-2 placed in them by Dr. Durrani at their facility without warning them, with full knowledge they were not warned.

114. Gerry Goodman knew anesthesia charged per the minute or in fifteen-minute increments and she considered it a fraud to bill for unnecessary anesthesia when patients were "open" longer than necessary.

115. Dr. Durrani would contact Medtronics and other vendors directly, they would bring into the OR what Dr. Durrani requested and then invoice West Chester/UC Health.

116. During surgeries, Medtronics and other vendors would want to up sell products.

117. This process was distracting to the OR staff and affected patient care.

118. Dr. Durrani told Gerry Goodman Dr. Shanti had privileges but wasn't yet on all the insurance panels.

119. Gerry Goodman asked Dr. Durrani: "Which panel so he's not doing those cases?"

120. Dr. Durrani told Gerry Goodman in response: "We're doing these procedures together. They're billed under my name."

121. Gerry Goodman witnessed one case where Dr. Durrani was never in the room at all, just Dr. Shanti. Yet, Dr. Durrani claimed the procedure.

122. Gerry Goodman confronted Dr. Shanti and he simply stated: "Dr. Durrani and I are co-surgeons."

123. Gerry Goodman verified Dr. Shanti was not on the written informed consents for these procedures.

124. Kevin Joseph, MD, and President of West Chester Medical Center, knew everything Gerry Goodman complained about because either she told him, or George Caralis told him. Caralis told her he told him.

125. Dr. Durrani had no supervision at all at West Chester/UC Health.

126. When Gerry Goodman attempted to supervise him, the West Chester/UC Health management as described here rebuked her.

127. Gerry Goodman also informed Mitch McCrate, Jill Stegman, David Schwallie, George Caralis and Kevin Joseph, MD, that Dr. Durrani's high volume of fusions of the spine was not usual practice. They ignored these concerns.

128. West Chester/UC Health's board and management, did not provide proper supervision of Dr. Durrani as required through the surgery and orthopedic departments. (See Bylaws section to follow)

129. Gerry Goodman also spoke to the Chief of Surgery at West Chester Medical Center about Dr. Durrani to no avail.

130. The West Chester/UC Health manager who did analytics and kept records sent to Gerry Goodman at her request, months' worth of their BMP tracking. She kept it and still has it.

131. West Chester/UC Health has previously denied tracking BMP-2. They lied. They tracked it to analyze the profit. They liked the profit. They encouraged Dr. Durrani to place all the BMP-2 he could.

132. Based upon Gerry Goodman's documentation, Plaintiffs have requested and expect to receive all BMP-2 tracking as evidence of Plaintiffs BMP-2 claims.

133. West Chester/UC Health's board and management increased the cost of the surgeries of Plaintiffs and patients by using BMP-2 infuse.

134. Dr. Durrani would also sign operative reports he never dictated with the full knowledge of West Chester/UC Health's board and management. This is yet another practice Gerry Goodman complained about.

135. Kate Fenner, PhD, owner of Compass Clinical Consulting, told Gerry Goodman that she had a meeting approximately 2007/2008 at West Chester Hospital with Kevin

Joseph to alert him to Durrani's billing and medical practices. Kate Stated that she knew Dr. Durrani was leaving prescriptions unsigned for his office nurses to distribute as needed when he was out of the country. Kate then stated that she knew Kevin knew about the questionable billing practices and was told **"WE NEED THE CASES AND THE REVENUES."**

136. Dr. Shanti dictated operative reports he never signed with the full knowledge of West Chester/UC Health's board and management. They knew because Gerry Goodman complained.

137. Orthopedics and spine surgeries are some of the highest sources of income for a hospital and were too for West Chester/UC Health.

138. In the spring of 2013, Dr. Peter Stern told Dr. Angelo Colosimo, UC Orthopedic Surgeon that West Chester/UC Health "knew all about Dr. Durrani's issues before he came to us and after he came to us, but we needed the money."

139. The billings for Dr. Durrani surgeries were sent to Plaintiffs at their homes with requests for payment.

140. Plaintiffs were required to make payments of uncovered medical bills to Dr. Durrani and CAST.

141. Dr. Durrani produced, distributed and utilized a video of a lecture involving his EDS patients to solicit more patients.

142. Unbeknownst to his EDS patients, Dr. Durrani was doing experiments on these EDS patients including many of the Plaintiffs without informing them they were part of an experiment. This too violated West Chester Medical Staff Bylaws as revealed in a later section.

143. Dr. Durrani claims in his EDS video a 95% success rate with the C1-C2 operations and only one of the twenty-five claimed they would not have the surgery again.

144. The undersigned counsel represents 20 of these 25 persons and not one would have the surgery again. They are Plaintiffs.

145. Dr. Tayeb was an employee of Dr. Durrani from 2009 to 2013. Counsel has interviewed him extensively.

146. Dr. Tayeb will testify that Dr. Durrani improperly selected patients for surgery, and then recommended surgery, including patients with EDS that were not proper candidates for surgery including many of the Plaintiffs.

147. Dr. Tayeb will testify that improper business practices occurred at CAST, including Dr. Durrani recommending surgeries that were medically unnecessary including the Plaintiffs.

148. Dr. Tayeb will testify that Dr. Durrani made decisions to place wealth and status over the well-being of his patients including Plaintiffs.

149. Dr. Tayeb, Dr. Durrani's pain management doctor for a time at CAST, reports that Dr. Durrani's misuse of BMP-2 resulted in bony overgrowth, where "it's like a big block of bone back there where you can't even stick a needle there anymore" and patients, including Plaintiffs would develop neuropathic pain.

150. Dr. Tayeb could not reach the nerve in many of the BMP-2 patients to even treat with injections.

151. Dr. Tayeb would engage Dr. Durrani in shouting matches at CAST over patient care that others witnessed.

152. According to Dr. Tayeb, Dr. Durrani would not always speak truthfully about patients having already gone through conservative care.

153. According to Dr. Tayeb, Dr. Tayeb believes West Chester knew about Dr. Durrani's prior issues.

154. According to Dr. Tayeb, surgical notes were not being done timely and there are some "clinical ramifications."

155. According to Dr. Tayeb, many times surgeries were performed in different areas than the work up.

156. According to Dr. Tayeb, patients would not understand what Dr. Durrani was doing.

157. According to Dr. Tayeb, Dr. Durrani loved to tell patients he would "fix" them.

158. According to Dr. Tayeb, Dr. Durrani told patients they would be paralyzed.

159. According to Dr. Tayeb, Dr. Durrani exaggerated the diagnosis of lumbar degenerative disc disease and stenosis.

160. According to Dr. Tayeb, ER patients with back pain were referred to Dr. Durrani.

161. According to Dr. Tayeb, he heard about West Chester facing financial challenges.

162. According to Dr. Tayeb, he is of the opinion Risk Management knew about Dr. Durrani issues.

163. According to Dr. Tayeb, Paula Hawk at a meeting with Dr. Durrani, Dr. Tayeb and Brian Gibler (CEO UC Health said: "We work with Dr. Durrani. We cater to Dr. Durrani, you know, to point where we want to try to expedite and make everything easy for you guys to bring everything over here." "He's our partner in crime."

164. According to Dr. Tayeb, there were a suspicious high number of spine surgeries.

165. According to Dr. Tayeb, Dr. Durrani bragged in the halls he was the top money maker.

166. According to Dr. Tayeb, he's aware of at least one time four (4) surgery suites reserved at one time for Dr. Durrani.

167. According to Dr. Tayeb, West Chester advertised they were a premier spine institute.

168. According to Dr. Tayeb, there was a discussion about CAST and West Chester co-oping and Dr. Durrani wanted a "piece" of the action.

169. According to Dr. Tayeb, there were $100 a day fines for records over 30 days late. He has no idea if Dr. Durrani was fined.

170. According to Dr. Tayeb, Dr. Durrani went an entire six months—no records.

171. According to Dr. Tayeb, there were also issues of too long of days in surgery.

172. According to Dr. Tayeb, Dr. Durrani had two heart attacks and would get sick, go to ER get fluids and keep operating.

173. According to Dr. Tayeb, Dr. Tayeb believes Dr. Joseph had to have knowledge of the issues.

174. According to Dr. Tayeb, Dr. Durrani was super aggressive.

175. According to Dr. Tayeb, seen in clinic to surgery scheduling was for 30 patients 20-30% for Dr. Durrani.

176. According to Dr. Tayeb, others for 30- one or two scheduled.

177. According to Dr. Tayeb, Dr. Durrani would schedule surgeries without looking at MRI or ordering one.

178. According to Dr. Tayeb pertaining to Dr. Durrani, "I think it was just everything that was walking needed to be cut on in some way, shape or form whether it was necessary or not."

179. According to Dr. Tayeb, Defendants held discussions with Dr. Durrani regarding using 4th floor of hospital for CAST rehab.

180. According to Dr. Tayeb, lack of documentation effects patient care and West Chester responsible.

181. According to Dr. Tayeb, he heard the "paralyze" and "severe stenosis" to patients from Dr. Durrani a lot.

182. Elizabeth Dean was employed at West Chester Medical Center before they opened the doors for business.

183. Elizabeth Dean was one of the original patient access representatives at West Chester Medical Center, which is now West Chester Hospital, beginning employment in February 2008 to July 2010.

184. Elizabeth Dean had many responsibilities within the hospital including admitting Dr. Durrani patients and completing financial reports for the West Chester/UC Health CFO, Mike Jeffers.

185. Elizabeth Dean was also included in most corporate meetings where discussions took place over the mass injections performed by Dr. Durrani in the testing area of the hospital and she also was the actual patient access representative who registered and spoke with all the Durrani patients.

186. According to Elizabeth Dean, before Dr. Durrani began to practice at West Chester Hospital, every area of the hospital was a "ghost town."

187. Despite being a new hospital, it was still not picking up revenue as it expected.

188. Elizabeth Dean was required to ask for all copays when the patients arrived, just to "keep the numbers up" as much as possible.

189. Elizabeth worked for five years as a medical biller with University Internal Medicine Associates before coming to West Chester.

190. Elizabeth Dean knew West Chester/UC Health needed money based upon her position and work at West Chester.

191. Elizabeth Dean reviewed the final numbers from CFO Mike Jeffers each month and also logged all payments received on the surgery cases including Dr. Durrani's.

192. West Chester/UC Health's board and management gave staff raises based upon the hospitals financial woes.

193. West Chester/UC Health fired the original CEO and corporate employees once the hospital was bought by UC Health, and appointed an ER physician as the new CEO, Kevin Joseph, MD.

194. Elizabeth Dean will testify that West Chester/UC Health decided to have West Chester/UC Health ran by physicians.

195. Vickie Scott worked at West Chester in the operating room during the time Dr. Durrani also worked there.

196. OR Nurses, including Vickie Scott, went to the OR management, Elaine Kunko and Denise Evans and to Risk Management, Jill Stegman, about Durrani's illegal activities, deviations in standard of care and violations of policies, bylaws, regulations and rules. No action was taken. They complained and reported the same issues Gerry Goodman reported as previously described.

197. Vickie Scott informed Elaine Kunko, OR assistant manager, about Dr. Durrani making the records appear that Dr. Durrani was doing all the procedures when they knew it was Dr. Shanti. Kunko did nothing to stop the Shanti Shuffle.

198. Scott Rimer, circulating nurse at West Chester Medical Center, spoke up and complained about Dr. Durrani at an OR meeting with OR staff and hospital administration. Not only was Scott Rimer ignored, the next day he had his supervisor standing next to him watching his every move. He was fired soon after.

199. In summary, Gerry Goodman, Vickie Scott, Scott Rimer and other OR staff members complaints to management included the number of Dr. Durrani surgeries he did a day and at a time; other surgeons performing surgeries for him without proper consent; Dr. Shanti not having proper qualifications and provider numbers; BMP-2 was tracked by the hospital despite their denials of doing so; Dr. Durrani was verbally abusive to everyone; anesthesiologists had to have patients "under" longer than they should have been; off label use of BMP-2 was not covered by informed consent; Medtronic reps would "up-sale" during surgeries; operative reports were not timely completed; Dr. Durrani had no supervision by the hospital; keeping OR staff past the time it was safe.

200. Those Gerry Goodman, Vickie Scott, Scott Rimer and other OR staff members complained to included Mitch McCrate, Jack Talbot, George Caralis, Kevin Joseph, MD, Melissa Hemmer, Elaine Kunko, Denise Evans, Jill Stegman, and David Schwallie. All of these individuals are and/or were West Chester/UC Health management who communicated these complaints to the board. Many like Kevin Joseph, MD, President were on the board.

201. West Chester/UC Health, its board and management, also knew of Dr. Durrani's sexual harassment of OR nurses and staff and ignored it.

202. Melissa Dowler witnessed Dr. Durrani offer a nurse in the OR $10,000 for oral sex.

203. Dr. Durrani had an affair with his staff member, Beth Garrett, who dropped out of nursing school, and like his relationship with a prior physician assistant at Children's Hospital, Jamie Moor it affected patient care.

204. Dr. Durrani, by his deposition testimony, admits he relies upon his own reading of radiology. Of course, in this manner he would recommend a surgery the radiology did not support. The radiology department at West Chester, the director of radiology and all the radiologists privileged at West Chester from January 1, 2009 to June 1, 2013, knew Dr. Durrani was ignoring their radiology interpretations and did nothing to address the issue and/or were ignored when they tried to address the issue.

205. Dr. Durrani, by his deposition testimony, admits he informs the pain doctor where to inject medicine. By doing so in the wrong place, he convinced many Plaintiffs to have repeat surgeries.

206. Melissa Garrett is forty-one (41) years old, and is a pharmaceutical salesperson in Tampa, Florida. Melissa Garrett said her sister Elizabeth "Beth" Garrett who worked for Durrani/CAST.

207. Melissa Garrett contacted counsel and stated that Beth Garrett was holding herself out as a nurse, although Beth Garrett had failed out of nursing school.

208. Melissa Garrett stated that Beth Garrett had been present during surgeries by Dr. Durrani.

209. She stated that Beth Garrett had improperly assisted in surgical procedures performed by Dr. Durrani without a nursing license.

210. She stated that Beth Garrett had been improperly selling pharmaceutical products, without a license.

211. She stated that Beth Garrett was having an "affair" with Dr. Durrani, and that she was concerned after Beth Garrett brought Dr. Durrani to her son's elementary school function and that the family "freaked out" in response to Beth Garrett and Dr. Durrani's conduct during the school function.

212. Dr. Durrani prescribes a custom compound cream he sells to patients without informing them which he bills to their insurance and just sends to them.

213. On information and belief Dr. Durrani owns some interest in this compound cream in a physician owned distributorship (POD) arrangement.

214. Shauna O'Neal followed Gerry Goodman to West Chester as Director of Nursing.

215. Shauna O'Neal came from Compass Clinical Consulting group in Cincinnati.

216. Shauna O'Neal wrote a letter to Tom Daskalakis the COO of West Chester/UC Health, Kevin Joseph, MD, and the CNO in which in which she reiterated what Gerry Goodman reported regarding Dr. Durrani's OR bookings and Dr. Shanti's lack of credentials and/or privileges. She was ignored.

217. Thomas Kunkel, MD, anesthesiologist, complained to West Chester/UC Health's board and management about Dr. Durrani's high number of "add on" patients. He was ignored.

218. According to Gerry Goodman, Dr. Durrani did add on patients at the last minute and after regular business hours so there was no one to preauthorize patients or question Durrani in any way regarding the surgery.

219. Dr. Durrani always told Thomas Kunkel, MD the surgeries were emergencies.

220. At times anesthesiology demanded the Chief of Surgery to intercede to judge whether or not it was emergent.

221. Cindy Traficant was Periop Director before and after West Chester opened.

222. When UC Health took over, Julie Holt, the original CNO, quit.

223. Cindy Traficant became interim CNO.

224. Cindy Traficant had a reputation of tolerating "bad" physicians.

225. West Chester Surgery was nicknamed by staff at West Chester/UC Health the "island of misfit" doctors because they took in and tolerated any doctor no matter their ethics, including Dr. Durrani.

226. OR staff collectively reported Dr. Durrani issues to West Chester/UC Health board and management and their complaints were ignored.

227. Dr. Durrani would sometimes, because he was running behind, cancel part of a surgery or do only part of the surgery, thus requiring the patient to have another surgery, all without informing the patient the cancellation was because he was late.

228. Dr. Durrani performed 159 surgeries at West Chester Medical Center in 2009; 534 in 2010; 536 in 2011; 437 in 2012; and 157 in 2013 for a total of 1,823 surgeries.

229. West Chester/UC Health admitted in a discovery answer in the *Shell* case that for the investigation, background check and the information used to decide to grant Dr. Durrani privileges they relied upon in part:

a. Dr. Durrani's education.

b. Dr. Durrani's training and experience.

c. Copies of his licenses and DEA numbers.

d. Inquiry to the National Practitioners Data Bank.

e. Evidence of required continued education.

230. West Chester/UC Health refuses to provide under a claim of privilege all persons they consulted prior to permitting Dr. Durrani privileges.

231. Dr. Durrani total **surgeries** performed as answered in a discovery in *Shell* at West Chester is as follows:

2009: 665

2010: 1908

2011: 1736

2012: 1102 (Through 9/30/12)

232. Dr. Durrani admitted as **inpatient** based as answered in a discovery answer in *Shell* at West Chester is as follows:

2009: 154

2010: 488

2011: 507

2012: 305 (Through 9/30/12)

233. Dr. Durrani admitted as outpatients based as answered in a discovery answer in *Shell* at West Chester is as follows:

2009: 13

2010: 41

2011: 45

2012: 35 (Through 9/30/12)

234. West Chester/UC Health refuses to provide under a claim of privilege their investigation to determine Dr. Durrani's fitness to practice medicine prior to permitting Dr. Durrani privileges.

235. West Chester/UC Health refuses to provide under claim of privileges, the instances where Dr. Durrani did not follow proper medical documentation protocol, policies and/or procedures at West Chester/UC Health.

236. West Chester/UC Health refuses to provide under claim of privileges, the complaints made by employees, staff or patients related to Dr. Durrani.

237. Dr. Durrani oftentimes used PureGen when performing surgeries, if this case involves PureGen, this is noted within this Plaintiff's specific factual allegations addressed earlier in this Complaint.

238. PureGen has never been approved by the FDA for any human use. It's also now off the market for any use.

239. Doctor Atiq Abubakar Durrani used the product PureGen in his capacity as a medical doctor in spines in the same manner BMP-2 was used.

240. West Chester/UC Health assisted Dr. Durrani in his use of PureGen at their facility.

241. A representative from Alphatec Spine was in the operating room during medical procedures per the Nursing Intraop Records when Dr. Durrani used PureGen.

242. A representative from Alphatec Spine was in the operating room during medical procedures even when the Nursing Intraop Records do not indicate so.

243. Dr. Durrani was and is a paid consultant for Alphatec Spine.

244. Dr. Durrani has an ownership stake in the Alphatec Spine.

245. Dr. Durrani provided PureGen to patients who required surgery and those who did not require surgery without Plaintiffs knowledge and consent.

246. Dr. Durrani performed unnecessary surgeries using PureGen on his patients.

247. West Chester Hospital, UC Health and the Center for Advanced Spine Technologies knowingly created false medical records, bills, and cost reports that included charges for unlicensed uses of PureGen, which resulted in inflated outlier payments to be paid by the government and other insurers using the Plaintiffs' right to make a claim; or in the alternative, causing a false cost reports.

CHRONOLOGICAL FACTUAL ALLEGATIONS

248. On January 1, 2009, Durrani opened the Center for Advanced Spine Technologies (CAST).

249. In February of 2009, Elizabeth Dean began working at West Chester where she prepared reports for Mike Jeffers on Dr. Durrani's billings. She testified Mike Jeffers was excited about what he read on the spreadsheets.

250. In February of 2009, Mike Jeffers, Director of Finances joined West Chester (He stays until January 2012). The director of finance admitted West Chester/UC Health tracked Dr. Durrani's financial numbers. He admits Dr. Durrani helped them in their "time of need." Dr. Durrani was the highest money generator. He knew Dr. Durrani had more than one surgical suite assigned at once. Bonuses were paid on finances.

251. In February of 2009, Carol King, Senior VP, joined West Chester. She ran it before Dr. Joseph. She would stay until April 7, 2010. She was discharged and testified:

"They didn't want me there anymore." Carol King was the first person in charge of West Chester was fired and ordered by counsel not to disclose the reason. She was a patient safety-first thinker. She did not explore the "rumors" about Dr. Durrani's leaving Children's.

252. In May of 2009, Medical Staff Office Policies and Procedures were adopted by West Chester (Peer Review)- Paula Hawk, Director of Medical Staff and Ed Crane, President of Medical Staff.

253. In May of 2009, Dr. Tim Kremchek, MD joined the staff of West Chester. He remains. He's always been the Director of Orthopedics. The Chief of the Orthopedic department failed to do his job under the MEC bylaws as it related to Dr. Durrani. He knew Dr. Durrani was a "sloppy" spine surgeon yet did nothing.

254. In May of 2009, Elaine Kunko joined West Chester from the beginning. She remains. She has held various jobs from daily operations coordinator of OR to Asst. Nurse Manager. She's now a coordinator in quality management. She testified West Chester knew about Dr. Durrani not completing records. They knew Dr. Durrani would claim surgeries were emergency. They knew there was an issue with Dr. Durrani not being in the room doing surgery on "his" patient. Even the OR nurses knew they put up with Dr. Durrani for money. West Chester tracked Dr. Durrani's numbers.

255. In May of 2009, West Chester Hospital opened.

256. In May of 2009, Vickie Scott began working at West Chester Hospital.

257. In May of 2009, Dr. Durrani was privileged at West Chester.

258. In June of 2009, AAOS Advisory on Consent BMP-2 (Off-Label) was published. West Chester/UC Health received it.

259. On July 7, 2009, a warrant was served to Dr. Durrani for assault of his wife. West Chester/UC Health learned of this fact.

260. The surgery schedule of Dr. Durrani shows an overwhelming number of surgeries Dr. Durrani was doing to the delight of the officers, management, Board of West Chester and Defendants. It's to support all claims.

261. The chronological sequence further fulfils the requirements under R.C. 2305.251 that Defendants knew of Dr. Durrani's "pattern of incompetence," "otherwise inappropriate behavior" and "fraudulent medical treatment" and their fraud.

262. On September 2, 2009, Jane Dresselhaus emailed Rohlfing and Hawk regarding a complaint about Dr. Durrani not doing progress notes.

263. On September 7, 2009, Rohlfing sent an email to Durrani – "Dr. Durrani – We have not been seeing progress notes on your patients and the patient below is one example. Obviously, this is a JCAHO and 3rd party requirement of many payors. Please help us avoid the exposure of these violations. Thank you – Ron."

264. On September 8, 2009, Ron Rohlfing sent an email to Dr. Durrani- Complaint- "We have not been seeing progress notes on your patients…"

265. On October 5, 2009, Elaine Kunko emailed Marc Feldman, Carol King, Cyndi Trafficant, Ann Simpson- Informing Dr. Durrani is buying products off contract- Orthovita, Trans One, Vitoss, Vitagel, AxiaLIF, Interventional Spine, Perpose, X Close, X2M.

266. On October 26, 2009, Paula Hawk sent an email and copied to Ron Rohlfing, Gina Witko and Cyndi Trafficant regarding a complaint that Dr. Durrani did not timely discharge patients.

267. In 2009, West Chester's Net Loss was $13,319,102.00.

268. In 2009, there were 159 total West Chester Durrani Surgeries for the year.

269. In 2009, Lesley Gilbertson, MD left West Chester.

270. On March 5, 2010, Elaine Kunko sent an email to Debbie Blimline and copied to Denise Evans. Complaint- Dr. Durrani not marking a surgical site before bringing the patient into OR.

271. On April 7, 2010, Carol King, Senior VP was fired.

272. On April 8, 2010, Kevin Joseph, M.D. becomes President of West Chester. He also is on the ER staff there. He's also a Senior VP of UC Health. He remains in these positions. Per his deposition: The CEO claims to know nothing about surgery operations is his hospital. The CEO claims a hospital must protect patients from unnecessary harm "as much as they can." The CEO claims they don't have oversight of surgeons doing what all plaintiffs claim Durrani was doing (despite what his bylaws state). The CEO denies the hospital has any responsibility if Dr. Durrani did an unnecessary surgery. The CEO, despite his finance office tracking it, denies any knowledge of BMP-2 use. The CEO, denies knowing about any complaints about Dr. Durrani. The CEO admits they benefited financially from Dr. Durrani, including his own pay.

273. On June 2, 2010, there was an email between Blimline and Joseph-"Just wanted to let you know that Dr. Durrani admitted two patients today and deemed them emergency procedures for tomorrow, Saturday 2/3/10. We have recruited extra people to do back up call for the OR as this will tie the OR call team up from approximately 0800-1500. I have consulted with Rosemary Kiser who is aware of the plan."

274. In July 2010, Elizabeth Dean left her employment at West Chester.

275. On July 2, 2010, there was an email from Joseph to Blimline- "Thanks for the heads up and keeping me in the loop. Do you know diagnosis and what makes them emergent operations? We should certainly keep track of these.

276. On July 2, 2010, there was an email from Blimline to Joseph-"HIPAA- Diagnosis Lumbar DDD, Lumbar Spinal Stenosis, and Procedure: Direct Lateral Interbody Fusion, L3-L4, posterior spinal fusion, L3-4, L4-L5 Laminectomy. I do not know the symptoms these patients are having that could possibly make them emergent. I do know he wanted to have the day scheduled tomorrow and we are not ready to grant that at this time. Yesterday in a meeting it was determined by George, Cyndi, and Rosemary that all of the costs would be considered before granting him Saturday time and this was communicated to his office yesterday when they tried to schedule this Saturday. I know there are other surgeons who have wanted Saturday time. My concern is if we offer it to Dr. Durrani for a few Saturdays and cover it with all staff (including anesthesia) on OT then other Drs. will also expect this to happen for them."

277. On July 2, 2010, there was an email from Joseph to Blimline- "Thank you for the info. I called Durrani to discuss urgency and explain significant cost implications, logistical implications with call team and also lifestyle implications with call team. Thank you for making me aware."

278. On July 2, 2010, there was an email from Blimline to Joseph/Trafficant/Rosemary Keiser- "I appreciate your follow up. I have a correction to make about the earlier information. The patients were admitted on Wed and they were told their cases would be on Saturday. This came from (Kathy/Melissa H.)

279. On August 2010, Gerry Goodman begins as Interim Director of Nursing in Operating Room at West Chester.

280. On August 6, 2010 Brian Isaacs, Medical Record Transcriptionist, informs law firm Santen & Hughes that Dr. Durrani privileges are suspended until his charts are completed (West Chester). Brian Isaacs confirms this suspension through at least October 5, 2010.

281. On August 23, 2010, there was an email from Gerry Goodman to Yvette Kauffman, Cyndi Trafficant, Debbie Blimline- "Durrani wants it a full day's schedule. States he has already booked 5 cases (which of course, he has not). He wants either to proceed with Monday cases or schedule them for the Saturday before. Your view?"

282. On August 27, 2010, there was an email from Goodman to Kauffman, Trafficant, Blimline, Willenborg, Parker, Kunko- "Please be aware that reps support Dr. Durrani have been bringing in trays "just in case." Dr. D does a case the Saturday before Labor Day. Sounds a little suspect to me."

283. On September 16, 2010, there was an email from Cyndi Trafficant to Kathy Lebowitz and Reply Same: Complaint Dr. Durrani wanted air cast splint. OR refused. He went to ED. Registered himself as patient and got an air cast.

284. On September 21, 2010, Durrani was still suspended, according to Isaacs.

285. On September 23, 2010, there was an email from Cyndi Trafficant to Kevin Joseph and Paula Hawk: Complaint- Durrani cases ran long and had to call in on call team. Resulted in another doctor taking a surgery to another place. "Schedules know that they are not to take Durrani's office staff word for how long a case will take." "Durrani played the system last night and stuck the team."

286. On October 5, 2010, Dr. Durrani still suspended at West Chester, according to Brian Isaacs.

287. On October 26, 2010, emails between Debbie Blimline and Cyndi Trafficant, Rosemary Keiser, Kevin Joseph regarding a complaint that Dr. Durrani runs late on cases outside his block.

288. On October 26, 2010, there was an email from Kevin Joseph, M.D. to Trafficant and Blimline- "For now, we will be sticking with the current scheduled, until 7 PM. With that said, we know that he has a habit of running late, which I am going to talk to him about and try to get under control. Also make sure the schedulers are using his average time of cases, not the time his office says it takes to do his cases. I agree with Cyndi, that if you want to schedule the staff on his days until 9 PM, so that they are scheduled instead of last minute late ending, then it may add job satisfaction to our nurses. At this time, we will not be extending hours until 11 PM."

289. In 2010, West Chester's Net Loss was $5,195,431.00.

290. In 2010, there were 534 total West Chester Durrani Surgeries for the year.

291. On February 10, 2011, there was a letter to Pam Kinane, Patient Advocate- copied to Kevin Joseph- 4 Pages- Complaint from Parent Regarding Dr. Durrani- Serious Care Issue.

292. On April 6, 2011, there was an email from Hanner to Cyndi Trafficant and Karen Ghaffari: Complaint- Dr. Durrani failed to see his patients- unhappy. "In addition, it raises the question if their medical needs were addressed."

293. In May 2011, Jeff Drapalik CFO joined West Chester. He is currently still there.

294. On May 4, 2011, there was an email from Jennifer Krause to mtaylor@castworld.com copy Wendy Gilkey- Complaint on four cases with insurance pay issues: 1. No operative report dictated. 2. "There is no MRI report or H&P to justify why this patient had this procedure." 3. There is no dictation. 4. No dictation.

295. On May 18, 2011, there was an email from Kevin Joseph to Mike Jeffers- Complaint about Dr. Durrani on hospital eating expenses on a case. Email from Paula Hawk to Kevin Joseph and Mike Jeffers- Complaint about Dr. Durrani -delinquent dictations, no clinical documentation, Aetna denial, Op notes are supposed to be dictated within 24 hours in our bylaws," My daily conversations with Dr. Durrani don't seem to be working.

296. In July 2011, the Medical Staff Office Policies and Procedures Adopted- West Chester (Peer Review).

297. On September 14, 2011, there was an email from Stegman to Joseph, Daskalakis, Rohlfing and Hawk reporting a lawsuit being filed against Dr. Durrani.

298. On October 15, 2011, there was an email from Janet Thompson to many including Hawk. "There was a patient that was going to go to 1 pct and at 2243 they said Dr. Durrani insisted that the patient go to 3 pct even though they were infected. That meant that 1 pct was to lose a nurse. I told them that they had to send a nurse home by 2 a.m. if they did not get an admission. Thanks, Janette E. Thompson MSN, RN Clinical Supervisor UC Health-West Chester Medical Center.

299. In 2011, West Chester's Net Loss was $8,365,918.00.

300. In 2011, there were 536 total West Chester Durrani surgeries for the year.

301. On January 2012, Mike Jeffers, Director of Finance, left West Chester.

302. On February 2, 2012, there was an email from Tom Blank to Durrani and Marc Feldman and Thomas Harris at UC Health - "Thanks for your time on the phone this morning to discuss Dr. Durrani's request for spine implant products. Back in November when we first submitted formulary pricing, we included all the Alphatec Spine products and met or exceeded your formulary pricing. FYI, since that time we have added products from Spinal USA per Dr. Durrani's request. Please verify that you have all the Spinal USA information. Dr. Durrani and Dr. Shanti have been utilizing the Alphatec Spine biologics including PureGen and Profuse. We are able to provide a great savings with many of the biologics products while providing implants that are approved per the indication and safe for use. After you speak to Tom Harris, I look forward to talking with you in regards finalizing the agreement. As mentioned, the terms and conditions have been signed, the pricing met, and all necessary papers have been submitted. I am at the ready to supply anything you need to move forward and take care of Dr. Durrani's request. Thanks again for your time and consideration as we look forward to furthering our relationship.

303. On April 19, 2012, Dr. Durrani had a seminar at West Chester (Claimed he was an Assistant Professor at UC and Children's when he is neither. West Chester allows this to happen.)

304. On May 16, 2012, there was an email from Heather Waugh to Debbie Blimline, Mark Tromba and Virginia Craig. Complaint - "post op sheets not being signed, and orders not being completed." "This is difficult to track MDs down to do orders, while taking care of two patients."

305. On May 17, 2012, there was an email from Mark Tromba to Heather Waugh, Debbie Blimline and Virginia Craig - "I know that the reason it has happened to Dr. Durrani is because his partner has not been here certain days to do his dirty work. This is going to continue, and I have talked to Dr. Durrani." "Most of the physicians are compliant." "Please let Ginney or I know about the issue when it happens again. (Because I know it will)." "Dr. Durrani has been addressed many times. What is the next step?" (Blimline response).

306. On July 6, 2012, there was an email from Kathie Hays to Mark Tromba - "He bold face lies. Does Kevin and Patrick know?"

307. On July 6, 2012, there was an email from Tromba to Hays - "Durrani screwed us over! Lied to Patrick and I about the patient being in too much pain to fly… the patient is having surgery tomorrow at his surgery center…. And one our instruments are going to!!! Kevin is being notified… not much else. Have a great rest of your trip! See you Monday!

308. On July 6, 2012, there was an email from Tromba to Hays -"Yeah, I asked him why his patient canceled for today and he said he couldn't fly because he was in so much pain. Yet was currently on a flight to Cinci. Patrick said he would address it with senior leadership… I'll update you on Monday!"

309. On July 20, 2012, UC Health began purchasing PureGen from Evolution Medical, LLC.

310. On August 6, 2012, there was an email from Kathie Hays to Virginia Craig and Mark Tromba - "It's a shame Durrani was actually here on time for the first time and we weren't able to get the patient started."

311. On August 6, 2012, there was an email from Joseph to Daskalakis – "Reporting new lawsuit being filed."

312. On August 27, 2012, there was an email from Tromba to Hays – Subject: RE: Attendance Certificate – Well Managed OR "Do I still get this even though we were talking to Durrani about cussing out Amy??"

313. On August 29, 2012, there was an email from Tom Blank to Griggs - RE: Evolution Alphatec Spine Par Level. Attachment: Evolution Medical West Chester MedAssets Biologics Par Level 071312.

314. On October 4, 2012, there was an email from Tom Blank to Willenborg and Griggs - "Yesterday, Paula asked me to help her find a PureGen vial and track it. I was able to track where the item was used and the patient's name. I don't have Paula's email or number, so I hope you can help here. Item 67010-050. Lot vial #AS3000 31470 Implanted HIPAA L5-S1 Fusion. Please confirm and let me know how this helps."

315. On October 4, 2012, there was an email to Griggs to Tom Blank - "I send the info to Paula, thanks for following up and thanks again for the heads up on the VToss."

316. On December 16, 2012, there was an email from Griggs to Sheldon & Hays - "Gary – Several of our Spine surgeons are consistently using Medtronic Magnifuse Bone Graft. The Rep. Dave Rattigan has been bringing this in for the surgeons to use for approximately one year. Since Infuse it not being used, our usage of Magnifuse has increased. To ensure the product is here, when we need it, we want to keep it on our shelf. Dave can supply us a Pyxis to keep the Magnifuse in. Also, this would be very helpful in tracking the bone product. I spoke with Kathy and she ok'd the Pyxis but

would like to run it by you before I give Dave the OK. Please let me know. Thank you, Becky

317. On December 19, 2012, there was an email from Sheldon to Griggs, Hayes and Dwayne Brown "Becky – UC Health's standard practice is not to accept equipment from suppliers. If additional clarification is needed, I recommend contacting Dennis Robb's office.

318. In 2012, West Chester's Net Loss was $8,366,000.00.

319. In 2012, there were 437 total West Chester Durrani surgeries for the year.

320. On January 2013, Dr. Thomas Brown left West Chester as Chief of Radiology.

321. On January 24, 2013, there was an email from Joseph to Durrani- "Atiq – I hope all is well with you, your family and your practice. Can you please review the below email and take some time to complete the below deficiencies ASAP? I know completing medical records is the most painful part of our jobs (I hate it too), but prompt medical record completion is needed for financial as well as medicolegal reasons. Thanks, Atiq. KJ (This matter involved a chart missing, a d/c summary and a $119,098.45 claim BWC would not process without it.)

322. On February 8, 2013, UC Health stops purchasing PureGen from Evolution Medical, LLC.

323. On March 6, 2013, there was an email from Tammy Benzinger to Tromba, Hays, Hawk, Stephens, and Talbot. "Today I was at the surgical desk and an employee stated to me that Dr. Durrani is going to get himself in a lot of trouble. He called an employee "Mexican" all the time and had just called another employee a Jew. As part of

management team, I felt I needed to pass this information along to the team. Thanks, Tammy."

324. In May 2013, the Policy "Stop the Line" Adopted at WCH.

325. In May 2013, Paula Hawk states West Chester begins a policy: "Stop the Line" A policy called "stop the line" was implemented the same year and month they kicked out Dr. Durrani. Paula Hawk admits at her deposition money is not supposed to trump patient safety. She admits peer review is for hospitals to protect each other. She admits hospitals are interested in volume, something Dr. Durrani provided.

326. On July 22, 2013, Federal Criminal Complaint against Dr. Durrani was filed.

327. On July 25, 2013, Dr. Durrani was arrested for Health Care Fraud and Making False Statements.

328. On July 27, 2013, Elizabeth Dean emailed Eric Deters providing information regarding Dr. Durrani at West Chester.

329. On August 2, 2013, Vickie Scott emailed Eric Deters providing information regarding Dr. Durrani at West Chester.

330. On August 7, 2013, Dr. Durrani was indicted.

331. On September 13, 2013, Dr. Durrani performed surgery on Dolores Scott, at WCH (Our last known Dr. Durrani surgery at West Chester. We were informed he left in May.)

SUMMARY OF ANONYMOUS EMAILS REGARDING DR. MEHLMAN

CONCERNS ABOUT DR. DURRANI 2005 THROUGH 2008

332. On January 3, 2001, Dr. Durrani received a notice called Physician Notification Letter, from Ellen Witsken, Associate Director, Health Information Management

Department… It lists two cases: one is 80 days late and one is 72 days late. The letter states: "Failure to complete these records within 30 days will result in automatic suspension of all non-emergency admitting and clinical privileges."

333. On January 20, 2003, Dr. Durrani sent a letter to Dr. Crawford negotiating his potential employment. Dr. Durrani's demands and requests are significant, and most are rejected.

334. In July 2005, Dr. David Stern became Dean of University of Cincinnati College of Medicine.

335. On November 11, 2006, 9:13 AM, Dr. Mehlman emailed Rick Brilli regarding industry support for the orthopedic spine fellowship. It is a long 9-point email with a conclusion expressing concerns of the conflicts involved with industry sponsoring the fellowship. Dr. Mehlman cites many articles in support of his position.

336. November 20, 2007, 10 PM, Dr. Mehlman emailed Dr. Wall "are you aware of the fact what would seem to have been an experimental procedure _____ was performed at our hospital _____? Are there policies/procedures to deal with such things???"

337. On November 21, 2007, 8:30 AM, Dr. Wall responded to Dr. Mehlman. Dr. Wall explains he believes it is just a surgical technique but states: "is a more radical departure from traditional fusion and is off-label." "What do you recommend for modifications to surgical procedures?"

338. On November 26, 2007, 12:40 PM, Dr. Mehlman responded to Dr. Wall. He states per his research at Children's and call with Kathie Hays, there is NO policy on FDA approved implants at our institution. He states Dr. Wall's examples in prior emails

were already adopted and supported by literature. He stated Dr. Durrani did a "spot fusion." He concludes with this: "Therefore, I would suggest to you that when a procedure deviates significantly from existing standard of care, when it has no identifiable literature support, and when it benefits are theoretical and its outcomes UNKNOWN- this might be a procedure that some would label EXPERIMENTAL… and this is why God created Institutional Review Boards and Ethics Committees and the like."

339. On December 14, 2007, 5:48 PM, Dr. Mehlman emailed Dr. Wall titled, "at least the 2nd complication like this I am aware of." He states: "Two of something is just different than one of something." He expresses patient safety concerns. He suggests a referral to Steve Muething's group. "The same patient I am showing you now also has one thoracic pedicle screw that is super close to the aorta."

340. On December 20, 2007 5:02 PM, Dr. Mehlman emailed Dr. Wall and attached a previous email and images. He states there are "at least two instances of "adjacent segment disease" in the form of upper thoracic spondylolisthesis occurring following pedicle screw instrumented kyphosis. He references he can't find other examples of the complication except a St. Louis paper says patients over 50 are higher risk. He states "Our CCHMC cases are clearly much less than 50 years of age- one was at least transiently paralyzed by the complication." He also states: "I would recommend to you that a root-cause analysis be undertaken regarding these cases- this would be aimed at PATIENT SAFETY. I would further suggest a moratorium on this technique until results of a review are in hand. This is prompted by the fact that it gets my attention when I see

a complication twice in relatively short period of time- especially a complication that I had not previously seen or heard about."

341. In 2008, Dr. David Stern became Vice President for Health Affairs at University of Cincinnati. From the College of Medicine website: "His focus was on building collaborative programs, especially with Cincinnati Children's Hospital Medical Center… and providing a foundation for the university's health system (UC Health).

342. On February 7, 2008, 2:03 PM emails Dr. Durrani requesting a moratorium on a procedure called upper thoracic spondylolisthesis above kyphosis constructs Dr. Durrani performed on kyphosis patients. Dr. Mehlman references Larry Lenke agreeing with Dr. Mehlman.

343. On February 7, 2008, 4:34 PM, Dr. Twee Do responded by saying "This is a very nice way to put it."

344. On February 7, 2008, 6:21 PM Dr. Durrani responded to Dr. Mehlman disagreeing with the moratorium.

345. On February 8, 2008 3:51 PM, Dr. Mehlman emailed Dr. Durrani referencing a new complication, calling it a patient safety issue, requesting a "root cause analyzed" and seeing how to prevent this from happening in the future.

346. On February 8, 2008, 5:48 PM, Dr. Durrani responded to Dr. Mehlman stating, "I do not think this needs to be root cause analyzed." He also states: "To make this a patient safety issue is inappropriate."

347. On February 8, 2008, 6:13 PM Dr. Mehlman emailed Dr. Durrani stating Larry Lenke as agreeing with him on the issue of the upper thoracic spondylolisthesis above kyphosis constructs.

348. On February 8, 2008 6:37 PM Dr. Durrani emailed Dr. Mehlman regarding the upper thoracic spondylolisthesis above kyphosis constructs. Dr. Durrani complains about addressing the issue by email and defends his conduct and claiming, "Just because Larry Lenke said it does not make it a scripture."

349. On February 15, 2008, 4:00 PM, Dr. Mehlman emailed Dr. Crawford and Dr. Durrani and copied to Dr. Do, Dr. Tamal and Dr. Wall regarding unsolicited feedback peds ortho fellows and residents regarding inability to participate in cases in the OR setting.

350. On February 15, 2008, 5:46 PM, Dr. Durrani responded to Dr. Mehlman that it was a legitimate concern.

351. February 21, 2008 is the date of an abstract titled: Preliminary Results of Safety and Efficacy of Minimally Invasive Correction of Spinal Deformity In Adolescent Idiopathic Scoliosis." It covered 5 cases. Between November 2007 and January 2008, five patients. 3 females. 2 males. Mean age 16.5 years. Pre-op. Cobb angle average 44.6. Post-op 13.8. Duration of surgery average 5.6 hours. Claims no complications. Wants to do a larger series.

352. On February 29, 2008, 4:41 PM, Lisa Thornbury emailed Albert Chavanne. Ms. Thornbury identified herself as Dr. Durrani's research coordinator. She referenced an IRB submission retractive on the minimally invasive correction of spinal deformity in AIS.

353. On February 29, 2008, 4:46 PM, Lisa Thornbury emailed Dr. Mehlman and Sherrie Powers: "per Dr. Durrani, Albert Chavanne will send protocol and I'll submit IRB for retro study."

354. On March 6, 2008, 9:46 AM, Dr. Mehlman emailed Dr. Wall complaining Dr. Durrani was performing an experimental procedure on a minor at Children's. He called it Minimally Invasive Correction of Spinal Deformity in AIS. He referenced bringing this to Dr. Wall's attention on November 20, 2007 when Dr. Mehlman believe it a non-IRB approved human experimentation. Dr. Mehlman claims the human research was submitted to the Scoliosis Research Society. He also referenced "the current faculty member" lists a patent on his CV for the experimental procedure in question. The email closes with "the only thing that concerns me more than taking a big issue like this to Dr. Azizkhan is not taking it to him."

355. On March 6, 2008, 2:02 PM, Dr. Mehlman emails Dr. Durrani withdrawing as a faculty member for the Children's Spine Fellowship. He copied Rich Brill, Janis Messer and Eric Wall.

356. On March 7, 2008, 3:14 PM, Dr. Stern thanks Dr. Mehlman for keeping him in the loop regarding "CORE Curriculum Conferences."

357. On March 14, 2008, 12:54 PM, Lisa Thornbury emailed Cassie Kirby, asking the difference between a case study and a research study for IRB purposes.

358. On March 17, 2008, 4:42, Cassie Kirby emailed Lisa Thornbury, explaining she believes it case study and recommends she contact Jeremy Corsmo of the IRB and/or Dawn-Lowe Gooden in Research Compliance.

359. On March 17, 2008, 5:11 PM, Lisa Thornbury emailed Cassie Kirby: "It's after the facts, so I have to figure out how to file… problem report with retro IRB submission to cover what already happened? Problem report with prospective protocol, but data is already collected?? Oh, the possibilities…. I'm not sure ePAS can handle some of the

situations I'm encountering! I think they may have to change language to retro if IRB requires them to still too new to know how IRB will respond."

360. On March 21, 2008, 6:08 PM, Dr. Mehlman emailed Dr. Wall. He references percutaneous scoliosis fusion surgeries. He believes it requires IRB approval protocol. He believes it is experimental. He believes legal should be consulted on consent. He states there is no human or animal subject literature in support and no IRB approval. He states: "To the best of my knowledge- this procedure is a dramatic departure from nearly 100 years of scoliosis spinal fusion evidence." He also states, "Scientific misconduct has already occurred in relation to this study insofar as a "preliminary report on the technique" ABSTRACT was submitted to IMAST/SRS."

361. On March 21, 2008, 11:36 PM, Cassi Kirby emailed to Dr. Mehlman titled Percutaneous Scoliosis Study. "CTM, Just as an FYI… This was Lisa's response… which pretty much confirms that nothing has been submitted to the IRB (problem report, protocol submissions, etc.). My interpretation of the response is that AAD is pushing to get his approved as a "retrospective stay. CASH. AAD is Dr. Durrani.

362. On April 2, 2008, 9:12 AM, Lisa Thornbury emailed Cassie Kirby and Dr. Mehlman and copied Dr. Durrani. "IRB determined that the following abstract is not human subject research. Preliminary results of safety and efficacy of minimally invasive correction of spinal deformity in AIS."

363. On April 2, 2008, 4:43 PM, Dr. Mehlman emailed Dr. Frenck, (John) and (Tracy) questioning Dr. Durrani's abstract.

364. On April 2, 2008 6:05 PM, Dr. Frenck emailed Dr. Mehlman supportive of Dr. Mehlman's concerns with the abstract.

365. On April 3, 2008, 8:37 AM, Dr. Mehlman emailed Dr. Frenck, "I would appreciate it if you are able to treat this as privileged communication. I am an abstract reviewer for the Scoliosis Research Society. Attached is the original abstract of the study in question- which as a reviewer "caught my eye." I later confirmed that the abstract came from my own institution and in fact no IRB existed. My PUBMED search shows no literature precedent for such a scoliosis procedure in animals or humans.

366. On April 3, 2008, 8:50 AM, Dr. Frenck emailed Dr. Mehlman, suggesting this talk about the abstract issue.

367. On April 7, 2008, 9:51 PM, Dr. Bob Frenck, IRB Chairman, sent an email to Dr. Durrani, informing Dr. Durrani to rescind his abstract submission because IRB is not allowed retrospective approval for projects. He cautions if there are others, same applies. He copies Dr. Wall, Jamie Bailey and Jeremy Corsmo.

368. On April 11, 2008, 2:10 PM, Dr. Mehlman emailed Dr. Wall "I wish to continue to raise concern regarding children undergoing spondylolysis surgery at our institution." He references two patients by name completed. He references four patients by name who are scheduled. He lists 13 more patients by name. He suggests outside reviewers. He suggests an internal review by Dr. Peter Stern, Dr. Guanciale and Dr. Asghar.

369. On April 12, 2008, 3:46 PM, Dr. Wall emails Dr. Mehlman and states: "I am most concerned about the patients who were recommended surgery without being given a trial of PT or bracing 1st. Do you have those names still? I had a similar case."

370. On April 12, 2008 at 5:10 PM, Dr. Mehlman emailed Dr. Wall and stated: "I do not have a sub-list of suspected "little or no effort" at non-operative care. In my opinion,

proper peer review of actual patient records would be necessary to make such a determination."

371. On April 12, 2008, 5:19 PM, Dr. Mehlman emailed Dr. Wall and requested Dr. Wall look at Article I of Children's bylaws regarding "Actions Affecting Medical Staff Members."

372. On October 1, 2008, 5:50 PM, Dr. Mehlman emailed Dr. Wall detailing Alex Taylor course of treatment with Dr. Durrani. Dr. Rohmiller agreed with Dr. Mehlman surgery for kyphosis not necessary. He asked Dr. Wall to "review the case on your own."

373. On October 2, 2008, 11:42 AM, Dr. Mehlman emailed Dr. Wall with more cases and names of questionable procedures.

374. On October 2, 2008, 12:52 PM, Dr. Mehlman emailed Dr. Wall regarding two kyphosis patients with complications, patients with the procedure referenced in the abstract and other cases. One was brought to his attention by Dr. Twee Do.

375. On October 2, 2008, 3:11 PM, Dr. Mehlman emailed Dr. Wall and provided 24 names of patients which Durrani did spondylolysis repair. He provided three names of patients who had "pedicle screws and some type of flexible implant that connects the screws." He gave the names of two others with questionable procedures.

376. On October 2, 2008, 3:18 PM, Dr. Mehlman emailed Dr. Wall another case which came through the pre-op/post-op conference.

377. On October 3, 2008, 6:01 AM, Dr. Stern emailed Dr. Mehlman and Dr. Wall: "Dear Eric: Dr. Mehlman has raised some serious issues here. I believe Dr. Durrani is fully entitled to due process but also think this apparently aggressive behavior might

warrant some type of independent evaluation. I believe as a profession we must exercise some oversight; especially when it involves patient well-being. Peter"

378. On October 10, 2008, 5:51 PM, Dr. Mehlman sent an email to Dr. Tamai in which Dr. Mehlman speaks of his work with Board of Certification, debates about standards of care, difference between standard of care and style of practice.

379. On October 11, 2008, 7:04 AM, Dr. Stern emailed Dr. Mehlman: "Chuck: Interesting dialogue. It is important for us to remember that there is usually more than one way to skin a cat. I use the 3 standard deviation rule: when you run a problem by 3 colleagues and they all agree that the selected treatment is 'out of bounds' it may be time to be openly critical."

380. Plaintiffs came into possession of a letter in May of 2018 which had been authenticated even in its absence at the time by Dr. Guanciale at his deposition on July 12, 2017. The letter proves that in 2008, Children's Hospital and their orthopaedic department, which included University and UC Health physicians, knew Dr. Durrani was a danger to any patient.

381. The letter states as follows:

October 20, 2009

Roy H. Thomas, MD, President
Ohio State Medical Association
The Elyria Eye Clinic, Inc.
850 East Broad Street
Elyria, OH 44035-6559

Dear Dr. Thomas and Members of the Ohio State Medical Association:

I am writing to you in regard to my concerns regarding a local orthopaedic surgeon and a situation that appears to involve poor surgical indications and, therefore, poor surgical decision making. Although I am sole author of this letter, this feeling is shared by many members of the orthopaedic community and, in particular, spine surgeons within the

community to a point that this concern resulted in some initial attempts at disciplinary action that I believe have failed to protect patients in our community.

The person in question is A. Atiq Durrani, M.D. Dr. Durrani is a physician who initially came to Cincinnati care through acceptance to a pediatric orthopaedic fellowship within the Orthopaedic Department at the Children's Hospital Medical Center. Dr. Durrani then, with continued interest in orthopaedic surgery, subsequently underwent application and acceptance for a United States based orthopaedic residency training at the University of Cincinnati within the Department of Orthopaedic Surgery. I am a member of the Department of Orthopaedic Surgery along with others, including Chairman Dr. Peter J. Stern. Dr. Durrani subsequently completed his residency program at the University of Cincinnati and this was followed by a one-year spine fellowship training in Louisville, Kentucky. He then returned to the Children's Hospital Medical Center in Cincinnati as an orthopaedic surgeon specializing in tumor surgery, pediatric spine surgery, as well as adult spine surgery.

During Dr. Durrani's short tenure at Children's Hospital Medical Center and within the Department of Orthopaedic Surgery, it was recognized by the greater Cincinnati community of spine surgeons, spine surgeons within the Orthopaedic Department and orthopaedic residents that Dr. Durrani displayed a pattern of surgical indications that would, by most standards, appear to be inappropriate. In particular, it was noted by all the above that it was not infrequent that a teenage patient with only intermittent back pain would be recommended an anterior/posterior fusion for treatment of symptomatologies where radiographic imaging would display minimal to no actual disc pathology. Similar situations arrived where patients were not infrequently under the ag of 18 recommended artificial disc replacements for, again, discogenic back pain. Patients were recommended fusion surgery for having completely normal diagnostic testing studies, including MRI examinations of the spine.

A recent abstract submitted to the North American Spine Society would also suggest that Dr. Durrani has been recommending operative treatment to nearly every adolescent patient that would present with back pain and some type of radiographic abnormality involving pars interarticularis region rather than conservative treatment which is effective in the majority of cases. I think it is also important to briefly note that this abstract submitted to the North American Spine Society for its meeting last November 2008 based in Toronto had to be retracted because the data was found to be falsified. It actually has been subsequently found by our own research review committee within the Orthopaedic Department at the University of Cincinnati that essentially no data existed for this abstract and its supposed results, therefore, constituting research fraud.

I would again like to reiterate that the observation of significant concerns about Dr. Durrani's surgical indications was voiced by many members of the Cincinnati medical community, all of which were relayed to our chairman, Dr. Peter Stern. This subsequently was brought up in a formal meeting and discussion with Dr. Durrani in the fall of 2008 during his employment with Children's Hospital Medical Center of Cincinnati, this including attendance by: the Chairman of the Department of Pediatric

Surgery, Richard Azizkhan, MD, the Director of the Children's Hospital Orthopaedic Program, Dr. Eric J. Wall, as well as Dr. Peter J. Stern. There were actually three separate areas of concern about Dr. Durrani's practice that were discussed at the meeting of which one involved his surgical indications. The other involved concerns about research fraud where he was submitting abstracts to medical societies without data or the actual project even existing and the third involving personal issues with employees. I did not attend this meeting but had direct involvement and discussions with Dr. Peter J. Stern since I am the Director of Spine Surgery within the Orthopaedic Department. Shortly after this meeting, Dr. Durrani voluntarily resigned from Children's Hospital Medical Center.

My concern, at this point in time, therefore, involves the fact that Dr. Durrani now is in private practice within the Cincinnati medical community and is under no structure that would allow for continued monitoring of his surgical practice, clinical skills and surgical indications. My concerns are that the same adolescent and pediatric patients that were receiving recommendations for very aggressive surgical treatment, such as artificial disc replacement and anterior/posterior fusions for situations not involving instability but rather dark disc disease, will continue unabated. The same members of the orthopaedic spine community that presented their initial concerns about Dr. Durrani's surgical indications, at this point and time, remain concerned as well. It is also very concerning that Dr. Durrani is attempting to establish a spine fellowship program to teach future generations of spine surgeons. I do not believe that Children's Hospital Medical Center has in place any program to suggest observation of Dr. Durrani's surgical practice at this time nor that they actually have jurisdiction to do such. I do not believe that they have actually contacted the Ohio State Medical Association in regard to these concerns.

Finally, I am concerned about the disproportionate number of severe complications that Dr. Durrani's patients have experienced, including death and paralysis that would be deemed to be unacceptable by the orthopaedic community for a competent spine surgeon. I am troubled by what many members of the medical community consider to be irresponsible surgical care that is being delivered to patients in the Greater Cincinnati area.

I, therefore, am contacting you expressing my sincerest concerns. I, as well as others are able to provide detailed, specific evidence to support the above. Although I am sole author of this letter, other spine surgeons within the Department of Orthopaedic Surgery at the University of Cincinnati, including Drs. Ferhan A. Asghar and Steven Agabegi, share these concerns and have read and signed this letter.

Sincerely,

Anthony F. Guanciale, MD
Associate Professor
Director, Division of Spine Surgery
Department of Orthopaedic Surgery
University of Cincinnati Medical Center

Ferhan A. Asghar, MD
Assistant Professor
Department of Orthopaedic Surgery
University of Cincinnati Medical Center

Steven Agabegi, MD
Assistant Professor
Department of Orthopaedic Surgery
University of Cincinnati Medical Center
Cincinnati Children's Hospital Medical Center

382. Durrani resigned from Children's on August 7, 2008, but it was not effective until January 1, 2009. He cited "inhospitable working environment." He addressed his letter to Dr. Azizkhan, but failed to mention the facts contained in the October 20, 2009 letter. On September 17, 2008, Dr. Eric Wall, as Director of Pediatric Orthopaedic Surgery of Children's sent a letter to Dr. Durrani's patients announcing Dr. Durrani's departure from Children's. There was no warning or disclosure of the meeting and facts described in the October 20, 2009 letter to any Durrani patient, the public or any regulatory agency.

383. On November 24, 2008, Dr. Durrani sent a letter to his patients announcing his departure from Children's on Children's letterhead. There was no disclosure of the facts described in the October 20, 2009 letter to any Durrani patient, the public or regulatory agency.

384. On November 24, 2008, on Children's letterhead, with University of Cincinnati logo on it, sent a letter to "Dear Valued Patients and Families" advising them December 31, 2008 was his last day as an employee at Children's Hospital. He included a form for them to complete if they wanted to follow him.

385. On February 12, 2009, 1:27 PM, Dr. Azizkhan emailed Dr. Durrani informing him if his patients are admitted at Children's, he is responsible as attending, but stated

GIS service can provide consultations and support as requested, and residents and fellows help on urgent Orthopaedic issues.

386. On February 13, 2009, 10:21 AM, Dr. Durrani sent an email including Dr. Azizkhan: "Hi everyone." It appears it also went to Dr. Wall and Durrani's staff. It is a coordination of patient care with Children's.

387. On February 15, 2009, 4:22 PM, Dr. Wall emailed Dr. Durrani making sure Children's and nurse stations have "proper contact numbers for you and your team at CAST.

388. On February 16, 2009, 5:34 PM, Dr. Durrani replied to Dr. Wall and copied Dr. Mehlman, Dr. Tamai, Sandy Singleton and Julie Hartmann he had given the numbers.

389. In Spring 2011, Dr. David Stern leaves the College of Medicine for University of Tennessee.

390. On July 26, 2013, 11:00 PM Dr. Agabegi sent an email to Dr. Stern, copied to Dr. Mehlman, Dr. Kuntz and Dr. Asghar where he copied an article about Dr. Durrani being sued for unnecessary surgeries and stated: "Looks like UC Health and CCHMC got some splainin' to do… Can't help but remember our meeting in the dean's office in 2011."

SUMMARY OF JULY 18 PRODUCED EMAILS AND LETTERS FROM DR. ASGHAR, DR. AGABEGI AND DR. STERN REGARDING DR. DURRANI FROM 2008-2013

391. **May 30, 2008 letter from Dr. Guanciale to Dr. Stern.**

Dear Dr. Stern:

I am writing this letter to you as a brief reference to my concerns about the clinical competency of Dr. Atiq Durrani. As we have discussed, I have had, I would consider, the unfortunate experience of seeing several of Dr. Durrani's patients as a non-referred second opinion after receiving fairly what I would describe as radical opinions about surgical treatment for their children. I believe there have bene five or six of these to date

over the past approximate year and a half. These have all involved extensive surgical procedures either involving recommendations for anterior fusion procedures or artificial disc replacement procedures in patients who are less than 20 years of age. None of these patients have involved any actual deformity or instability of their spine and have essentially had activity-related back pain, typically not constant pain, but rather with playing a particular sport. None of these had significant abnormalities on numerous radiographic studies including MRI's, as well as often bone scan, CT scans, even possibly CT discography tests, which would be an extremely uncommon test ordered in a young person or adolescent. The predominant portion of these patients simply had disc desiccation and some early discogenic changes on their radiographic studies, which I believe consistently throughout the country would be treated nonsurgically.

One recent such evaluation involved a patient, [redacted], who is a 17-year-old local high school student/athlete playing basketball and I believe soccer, who has back pain only after sports participation, and who has early disc desiccation changes and a small disc protrusion. [redacted] was specifically recommended an artificial disc replacement by Dr. Durrani. An artificial disc replacement in a 17-year-old with intermittent back pain that's non-debilitating would certainly lie outside of the standard treatment recommendations by I believe almost any spine surgeon in the country. Another such patient was a 14-year-old patient, who is a figure skater or attempting to be a figure skater, who was having difficulties with back pain symptomatology and rare leg pain, who had a disc herniation, who at most would've possibly benefited from a lumbar microdiscectomy type surgery.

She, however, in seeing Dr. Durrani was recommended an anterior and posterior lumbar fusion procedure with pedicle bone screw instrumentation for her intermittent ice skating related back pain. Her pain subsequently resolved with undergoing physical therapy, albeit over many months (greater than 6 months), and epidural steroid injections. Her pain has completely resolved at this time and she's returned back to figure skating without requiring any surgery.

I have provided these examples with one patient's name being included and I can provide other patient's names if necessary in order to attempt a convey information that establishes a pattern by Dr. Durrani of being overly aggressive in regards to surgical treatment suggesting very serious surgical procedures that have often high complication rates for underlying pathology that is very minimal in nature and often is treated nonsurgical. I believe this is a very serious concern, this clearly shows some difficulties in judgment in regard to clinical decision making. As we all know, just because we're surgeons, it doesn't mean that every patient needs a surgical procedure, let alone an extensive surgical procedure. As you know, and I believe as you practice, certainly most of our patients are treated non-surgically. I believe that this pattern of treatment is a concern for the residence of the Greater Cincinnati area and long term do not provide the treatment that they all desire and deserve.

Sincerely,

Anthony Guanciale

*This letter is very powerful and gives specific examples. Of note, it's May 30, 2008. It took months for the meeting.

392. **July 8, 2008 letter from Dr. Stern to Dr. Guanciale.**

Dear Tony,

I am in receipt of your letter dated May 30, 2008 regarding your concerns of Atiq Durrani, MD. As you will recall, we have informally discussed your concerns voiced and I have also spoken with Dr. Asghar and John Roberts, MD (both informally). Finally, I met in my office with Eric Wall, MD about a month ago regarding the withdrawal of Richard Owens' thesis presentation.

With your permission, I would like to setup a meeting with yourself, Dr. Richard Azizkhan, Dr. Eric Wall and myself.

I am very concerned about Dr. Durrani's activities and his indications for surgery. I also strongly believe that he is entitled to due process and I would think that a formal discussion is outlined above would be appropriate starting point.

I look forward to hearing from you and hope you are willing to meet with Drs. Azizkhan and Wall.

Sincerely,
Peter Stern

393. **July 14, 2008 letter from Dr. Stern to Dr. Wall**

Dear Eric,

This is a follow-up letter to our conversation in my office regarding Atiq Durrani on July 12, 2008. Three items were discussed in detail:

a. Dr. Durrani's indications for spine surgery appear to be overly aggressive.
b. Possible research misconduct (re PARS defect)
c. Human Resource issues.

We agreed that all three of these issues are potentially very serious. We further agreed that we will discuss these issues with Dr. Azizkhan in the presence of legal counsel to insure proper action and due process.

Sincerely,

Peter Stern

394. **July 29, 2008 letter Dr. Stern to Dr. Azizkhan and copied to Dr. Wall**

This is a delayed follow-up letter to our meeting two weeks ago regarding Atiq Durrani, MD. I received a phone call from a community spine surgeon who also expressed concerns regarding the aggressive nature of Dr. Durrani's indications for spine surgery in children. He told me that there are several other members of the Orthopaedic community that have seen patients for a second opinion who have voiced similar concerns. He told me that a list of names could potentially be produced.

Granted, this is hearsay. Nevertheless, I remain concerned about Dr. Durrani's indications for spine surgery in these young individuals. I appreciated the opportunity to speak with you and Dr. Wall and am encouraged that you will take the necessary steps to look into my concerns.

Sincerely,

Peter Stern

395. **September 24, 2008 letter from Charles DeRousie Vorys, to Elizabeth Stautberg, VP and General Counsel at Children's for Dr. Durrani.**

Dear Beth,

Thank you for taking the time to speak with me on September 12, 2008, regarding the transition of Dr. Durrani's employment with Cincinnati Children's Hospital Medical Center (the "Hospital"). I have discussed our conversation with Dr. Durrani as well as his obligations. He has asked me to respond to you in this letter.

The non-competition provision which was included in the Employment Agreement, dated October 15, 2003, has been the subject of conversation between Dr. Durrani and other representatives in the Hospital and our conversation. Both parties signed the 2004 Employment Agreement which explicitly states that "Dr. Durrani will not be subject to a non-compete clause in any contract concerning his employment at Cincinnati Children's." For the Hospital to now assert that a non-competition provision in a previous document somehow applies in view of that explicit language absolutely contradicts both the express language and intention of the 2004 agreement. It is clear there is no basis for the Hospital to assert that the non-competition provision must affect Dr. Durrani's future practice.

You also informed me that the 2004 Employment Agreement did not specify the compensation payable to Dr. Durrani, but merely sated the minimum payment. Dr. Durrani expects that his compensation through the end of his employment will be paid consistent with the calculation of his compensation prior to his giving notice of termination. This would include the bonus to which he is entitled.

Dr. Durrani is a "Member" as defined under the Faculty Practice Plan for the Division of Pediatric Orthopedic Surgery. Section VI.C of the plan provides for the payment upon termination. The second paragraph of that section specifically states "the above methodology in this Section VI.C shall also apply to individual Members who terminate employment from CHMC, provided, however that the Member ends his employment according to the norms and expectations of CHMC." Other than the assertion of the non-competition provision, which as set forth above does not apply, Dr. Durrani is not aware of any norms and expectations which have not been satisfied. To the contrary, Dr. Durrani has tried in every respect to facilitate the transition in the interests of both his patients and the Hospital. Thus, Dr. Durrani is entitled to be paid in accordance with Section VI.C of the plan.

As a physician leaving a practice, Dr. Durrani has a legal obligation imposed by the State Medical Board to communicate with his patients. That communication requires mailing a notice, publishing a notice and posting a sign in a conspicuous location in or on the façade of Dr. Durrani's office. This notice must advise his patients of their opportunity to transfer or receive their records. As his employer, the Hospital has an obligation to enable Dr. Durrani to satisfy his legal obligations incurred in connection with his employment. Thus, Dr. Durrani believes that the letter enclosed should be sent as required. If you would like to discuss the content of the letter, please let me know. The text of the letter will be the basis for the published notice and the sign.

We would also like to know what the arrangements are for the timely and appropriate mailing of the notice to all of Dr. Durrani's patients. By regulation, these patients are those seen by Dr. Durrani within the preceding three (3) years. If the Hospital does not want to mail the letter to Dr. Durrani's patients, Dr. Durrani would like a list of the patients and their addresses so he may mail the letter to them directly to satisfy his legal obligation.
Dr. Durrani is interested in resolving these issues as quickly as possible to enable the transition which will be in the best interests of the Hospital, his patients and Dr. Durrani. Please let me know when you would like to discuss these matters.

Very truly yours,

Charles S. DeRousie

Dear Valued Patients and Families:

This letter is to advise you that as of December 31, 2008, I will be leaving my practice with Cincinnati Children's Hospital Medical Center (CCHMC) and entering into private practice providing Orthopaedic care to both children and adults. My new practice will be called Center for Advanced Spine Technology (CAST). It will be located just north of Cincinnati in the West Chester area, convenient to both I-75 and I-71.

My years at CCHMC have been very rewarding, and it has been my sincere pleasure and privilege to have you or your family members as a patient under my care. Cincinnati

Children's is an excellent facility and though I am moving to new private practice offices, I will continue to perform procedures at the hospital.

On a personal note, I will miss the interactions that I have shared with my fellow colleagues, the many outstanding staff at CCHMC.

I look forward to continuing to care for your Orthopaedic needs at my private practice. If you wish to have your records transferred to my new practice, _____. If you wish, I will facilitate the transition of your care to a CCHMC physician. If you wish to receive your records, _____.

Sincerely,

Atiq Durrani, MD

PS. To reach me or to make an appointment at my new, private practice, please call 1-877-327-CAST (x2278) beginning _____.

***Remarkable they still allowed him to operate at Children's.**

396. **October 15, 2008 letter from Charles DeRousie, Vorys to Elizabeth Stautberg.**

Dear Beth:

This letter follows up the conversation you and I had on Thursday, October 9, 2008, and my letter to you dated September 24, 2008. The delay in providing the letter to patients and (what we understand to be) misinformation being given to patients and physicians inquiring about Dr. Durrani's future services are creating serious concerns for Dr. Durrani regarding his ability to appropriately serve his patients. The letter dated September 25, 2008 from Dr. Wall implies that Dr. Durrani would not see patients for follow up care, which is untrue, and does not inform patients how they can have records transferred to him.

It has been more than two weeks since I sent to you a proposed letter to be sent to patients. Although you told me that Children's Hospital Medical Center will enable Dr. Durrani to satisfy his legal obligations with respect to notification of patients, this delay is unnecessary. Combined with Dr. Wall's letter, the situation is clearly detrimental to the physician-patient relationship.

Further, notwithstanding the telephone number provided in that letter about how to communicate with Dr. Durrani, we understand that patient inquiries and inquiries from physicians about scheduling services are met with the response from hospital personnel that the Hospital does not have information about Dr. Durrani's future services. That is clearly untrue about misleading to patients and physicians. This, too, interferes with Dr. Durrani's ability to provide services to patients.

It is extremely important that we come to an agreement as quickly as possible regarding the proposed letter to patients, the notice to be published and the sign to be displayed in the office where Dr. Durrani's patients are served. This information needs to be provided as quickly as possible, not simply in order to satisfy the minimal requirements set forth in the regulations applicable to Dr. Durrani.

So that there is no mistake, any inquiries directed to the Hospital about scheduling of appointments with Dr. Durrani after December 31, 2008, should be met with the response that appointments can be made by calling 1-877-327-2278.

We have been informed that, in order for Dr. Durrani to obtain new malpractice coverage beginning after the termination of his employment with the Hospital, the successor malpractice insurer needs proof of the Hospital's payment of his "tail" insurance under his existing employment, beginning with the first day of employment through the current date. I am informed that the "loss run" is generally prepared by the current insurer and can be requested by the policyholder, the Hospital. We request the Hospital to provide such confirmation of "tail" coverage and the "loss run."

Article X of the Faculty Practice Plan provides for a conflict resolution mechanism in the event of a dispute. On behalf of Dr. Durrani, we hereby request that such procedure be used with respect to these matters. The dispute is described in this letter and in my letter of September 24, 2008, a copy which is included. We would like to schedule a meeting as soon as possible at a mutually acceptable time and place to resolve this dispute.

If you have any questions, please call me.

Very truly yours,

Charles S. DeRousie

397. **October 22, 2008 letter form Victor Walton, Vorys, to Dr. Wall, Dr. Azizkhan, Dr. David Stern and Dr. Peter Stern and James M. Anderson, CEO Children's.**

Gentlemen:

Pursuant to Section VII of the Faculty Practice Plan of the Division of Pediatric Orthopaedic Surgery of Children's Hospital Medical Center, attached please find a letter of October 15, 2008 which was sent to Elizabeth Stautberg invoking Article X of the Faculty Practice Plan to attempt to resolve the dispute between Children's and Dr. Durrani.

398. **August 26, 2009 letter version had only Dr. Guanciale's name on it.**

399. **Email dated August 28, 2009 5:49 PM from Joann Kaeser to Dr. Stern.**

"Will you please read over these?

Thanks,

Tony

400. **Email dated August 29, 2009 7:04 AM from Dr. Stern to Joann Kaeser and Dr. Guanciale.**

"Dear Joann:

I've made a few modifications. See attached.

As I noted, the ABOS is not a disciplinary organization; it only does certification. This needs to go to the Ohio State Medical Society; which does licensure.

P. Stern."

401. **Email dated September 30, 2009 3:42 PM from Joann Kaeser to Dr. Guanciale.**

"Letters on Dr. Durrani.

Joann"

402. **Email dated October 5, 2009 11:39 PM from Dr. Guanciale to Teri Lyons.**

"Teri please make the changes that Dr. Stern suggested and email me a copy. Thanks.

***This refutes Dr. Stern's deposition claim he never saw the 2009 letter.**

403. **Email dated October 8, 2009 9:54 AM from Teri Lyons to Guanciale.**

Dr. G,

Here are the corrections.

Teri"

404. **Email October 23, 2009 at 11:46 PM from Dr. Guanciale to Dr. Agabegi and Dr. Asghar.**

"Here is a copy of the Durrani letter.

Keep in mind as you get all these comments from "people" about his this needs to be reported, that the ultimate responsibility should have come from the director of orthopedics at Children's and from the chairman of the dept of orthopedic surgery.

This letter is CONFIDENTIAL and to be shared with no one if it is to be effective!!"

***Significant they want the director and chairman on the letter.**

405. **Email October 24, 2009 12:52 AM from Dr. Asghar to Dr. Guanciale and Dr. Agabegi.**

"I commend you for restraining the tone of your letter more than I would be able to…

I'm happy to cosign this with you and anyone else. I do wonder if this will simply get buried somewhere in the State offices and agree that PJS and Wall need to get involved too. A letter from the Chair of a department about a person who he trained (and who he would usually stand up for) a former president of the AOA- will carry more weight.

Do you think specific cases should be included at this stage? A list of ten cases will show that we aren't just a bunch of disgruntled former colleagues who have a bone to pick with him. Perhaps they should be reminded that this is not the first time they have been contacted about him.

It's absolutely amazing how long this has been allowed to continue.

FAA"

***Who had contacted the Board earlier and when?**

406. **Email October 26, 2009 at 11:16 PM from Dr. Agabegi to Dr. Guanciale and Dr. Asghar.**

"I made a couple of minor additions. Hope you don't mind. I added a small paragraph about complications… don't know if you want to include it. I think mentioning his complications gives the letter more "urgency"… that patients are at risk."

Dr. Agabegi added the following to the letter:

second page… bracing removed and added "which is effective in the majority of cases."

He added the final two paragraphs on page three:

"Finally, I am concerned about the disproportionate number of severe complications that Dr. Durrani's patients have experienced including death and paralysis, that would be acceptable by the orthopedic community for a competent spine surgeon. I am troubled by

what many members of the medical community consider to be irresponsible surgical care that is being delivered to patients in the greater Cincinnati area."

He added this to the final sentence and final paragraph:

"I am able to provide detailed specific evidence to support the above. Although I am the sole author of this letter, other spine surgeons within the Department of Orthopedic Surgery at the University of Cincinnati, including Dr. Ferhan Asghar and Steven Agabegi, shall these concerns and have read and signed this letter."

He added Dr. Asghar and himself at the end to sign.

407. **Email dated October 27, 2009 at 4:00 PM from Teri Lyons to Dr. Guanciale, Dr. Asghar, Dr. Agabegi, Dr. Roberts, Dr. Kahn and Dr. Rohmiller.**

"Dr. Guanciale,

Here is the corrected letter.

Thanks,

Teri"

408. **Email dated October 28, 2009 at 11:41 PM from Dr. Guanciale to Teri Lyons, Dr. Asghar, Dr. Agabegi, Dr. Roberts, Dr. Kahn and Dr. Rohmiller.**

"This is what I believe is a final letter."

409. **Email November 16, 2009 at 8:08 AM from Dr. Agabegi to Dr. Guanciale and Dr. Asghar.**

"He wants the letter sent to the Ohio State Medical Board not the Ohio State Medical Association. The president is Dalsukh Madia MD."

410. **Email November 16, 2009 at 11:33 AM from Dr. Guanciale to Teri Lyons.**

"Requesting a change on Dr. Guanciale's title. It included Interlaminar Enterprise, LLC."

411. **Email dated November 16, 2009 12:10 PM from Teri Lyons to Dr. Agabegi, Dr. Guanciale and Dr. Asghar:**

"Hi. Dr. Agabegi.

Dr. Thomas is not the president of the Ohio Medical Board, he is the president of the Ohio Medical Association. The Ohio Medical Association was Dr. Stern's suggestion of

where it should be mailed. I will change the letter and use Dr. Madia, but I am wondering if you think I should send it to him at the board's address in Columbus or his practice address in Marion. I am not sure which would be best.

Thanks, Teri"

412. **Email November 16, 2009 9:45 PM to Teri Lyons, Dr. Guanciale and Dr. Asghar:**

"I think it should be sent to the Ohio State Medical Board. I think Dr. Stern meant the board and may have mistakenly said "association." Board address would probably be better.

What is the status of the attorney reviewing the letter?

I spoke with Dr. Mehlman and he is on board with us… he knows one of the physicians on the board—this may be a good resource.

Dr. G: Any word from Roberts/Kahn/Rohmiller? Will they sign the letter? I know the letter was emailed to them, but did you want to ask them directly if they will sign? Do you want one of us to talk to them? Please advise. The more people involved the better."

-steve

413. **November 16, 2009 After 9:45 PM- email from Dr. Guanciale to Dr. Agabegi and Dr. Asghar:**

"I agree with the note about sending to the medical board.

I received the email back from Kahn, Roberts and Rhoemiller however no offer to cosign.

I think at this time instead of further delay it is best to just send the letter in a confidential status and allow the board to proceed.

I don't think an attorney needs to review any letter sent to the board as this is our responsibility.

I also found out at NASS that several people were unaware that Dr. Durrani's false research paper sent last year was indeed false and represented research fraud."

414. **Email November 20, 2009 at 10:29 AM from Dr. Asghar to Dr. Agabegi:**

"I sent it to Marcia, and she will forward to the attorney- I just went ahead and sent it in the form you had- I haven't been able to edit it and still be sensitive to all the political issues."

415. **Email dated November 26, 2009 at 10:25 AM from Dr. Asghar to Marcia Miladinov.**

"Marcia,

This is a sensitive issue, so we'd like to keep it under wraps.

Dr. Stern suggested sending this to the attorney to ensure there aren't any legal implications for us reporting him to the board. Drs. Guanciale, Agabegi and I are all on Board, and Dr. Stern will sign if reviewed by an attorney. Several other docs in town/CCHMC may sign it as well. Could you please forward to our legal counsel? We've been working on wording/what to say etc. for a while now, and at this point would like to get it done fairly soon.

BTW the letter in its current form is addressed to the president of OSMA, but we actually will be sending it to the Ohio State Medical Board. Thanks.

FAA

416. **Email December 20, 2010 at 6:10 AM from Dr. Stern to Dr. Asghar and Dr. Agabegi.**

Subject: FW: Top Spine Surgeons Reap Royalties, Medicare Bounty- The Wall Street Journal

"interesting; probably only the tip of the iceberg.

Peter"

***Article was attached.**

417. **Email December 20, 2010 at 11:52 AM from Dr. Agabegi to Dr. Asghar:**

"Durrani trained at Leatherman (the program they are referring to although interestingly the name Leatherman spine center was never mentioned… Norton is the name of the hospital). Should we contact wall street journal and tip them off? This would be perfect opportunity to expose this charlatan."

418. **Email December 20, 2010 at 4:27 PM from Dr. Asghar to Dr. Agabegi:**

"Missed your email. I was calling you to see if you wanted to write a response together, but it went to voicemail so I just drafted up an angry letter of my own. I figured it would be less official a response from UC if it was just from me or you. You should probably write one as well. You may make some different points, and maybe they'll be prompted to call us."

FAA

419. **Email February 20, 2011 at 1:07 PM from Dr. Stern to Rhonda Treat, Dr. Kuntz, Dr. Mehlman, Dr. Asghar and Dr. Agabegi.**

"Rhonda:

I'd like to set up a meeting w/ Dean Filak, Dr. Boat and Charlie Pangburn about Dr. Durrani regarding patient care issues- ½ hour.

Please include:

Drs. Mehlman (CCHMC); Kuntz (neurosurgery), Agabegi and Asghar.

Thanks, ps"

420. **Email March 7, 2011 at 8:17 AM from Rhonda Trent to at least Dr. Asghar:**

"I have been asked to setup a ½ hour meeting on Dr. Stern's behalf with the following people:

Dean Filak
Dr. Boat
Charlie Pangburn
Dr. Mehlman
Dr. Kuntz
Dr. Agabegi
Dr. Asghar

The key people being: Dean Filak, Dr. Boat, Charlie Pangburn, Dr. Stern, Dr. Kuntz

From the times Karen provided me for the Dean, Dr. Stern is in town and available the following:

March 31st (thurs): 4-7 PM
April 1st (fri): 3 PM or 5 PM

Please let me know your availability.

Thank you.

Rhonda
(She is the Executive Administrative Assistant and Peter Stern, MD and Marcia Miladinov)

421. **Email March 7, 2011 4:02 PM from Dr. Asghar and Rhonda Trent.**

"I'm available as late of poss on either dates b"

422. **Email August 30, 2013 4:23 PM from Dr. Asghar to Jared Camper:**

"Hi,

Well, it wasn't easy, but I found the name of the patient- it was _____. I could not find a note from Dr. Durrani in the electronic file. He may have left a note in the paper chart, which we could get if you'd like. Please let me know if there is anything further I can do to assist. Thanks. Ferhan Asghar."

423. **Email August 30, 2013 at 4:39 PM from Jared Camper to Dr. Asghar**

"Thanks Dr. Ferhan. Have a great weekend."

424. **Email September 3, 2013 at 12:06 PM from Jared Camper to Dr. Asghar and Rob Kotarski (FBI)**

"Hi Dr. Asghar. I hope you had a great, long weekend. During our meeting last week, you mentioned 2 prior Dr. Durrani patients you saw on whom you likely would not have performed surgery. From my notes, you saw one patient 2-3 years ago and the other patient just 1 week ago. Would you provide us the names and DOBs of these 2 patients?

Thanks, Jared

Jared Camper
Special Agent
DCIS Dayton RA

425. **Email September 3, 2013 at 2:43 PM from Dr. Asghar to Jared Camper:**

"Sure, will do.

I'm in the office tomorrow so should be able to get this to you. If I don't get back by the end of the week, please call/email me again to make sure it didn't fall through the cracks on my "to-do list"

FAA

426. **Email September 4, 2013 from Jared Camper to Dr. Asghar:**

"Dr. Asghar, just a friendly reminder to send me the names of those 2 patients… thanks."

427. **Email September 10, 2013 at 8:55 PM from Dr. Asghar to Jared Camper:**

"The patient I saw a couple of weeks ago is [redacted]. As mentioned, I didn't see her presurgical MRI so can't say it was entirely unindicated surgery. Some of the notes did look questionable though- radiology note made mention of grade 1 spondylolisthesis (mild and the most common) but his note said (severe spondylolisthesis) Also op note was dictated over 4 months later.

Second patient is [redacted]. She had a lumbar fusion surgery and says that he told him he would be doing a disc replacement, not a fusion. Also, have not seen pre-surgical MRI scans but doubt there was much pathology that warranted an operation.

How does it work in terms of patient confidentiality that I provide this info to you without patients' permission? I imagine they would be willing to speak to authorities about their experience, but I don't want them to be taken aback by a phone call without notice.

FAA

UNIVERSITY AND CHILDREN'S/WEST CHESTER INITIAL

CREDENTIALING OF DR. DURRANI

428. Dr. Stern is Chairman of the Department of Orthopedic Surgery at University of Cincinnati, so he is Dr. Mehlman's academic boss. (Mehlman pg. 127). UC Logo has been on Children's letterhead. (Mehlman pg. 150). University and Children's share training. (Mehlman pg. 150). Children's is the pediatric academic arm of the university. (Mehlman pg. 247). University of Cincinnati oversees us all. (Mehlman pg. 247)

429. "Some sort of effort to protect the public should've been undertaken" (Mehlman pg. 140). The announcement to patients from Children's when Durrani resigned should have included a warning. (Mehlman pg. 141). Dr. Mehlman remembers the secretaries in the office stuffing the letters about Durrani's practice location changing. (Mehlman pg. 141). Dr. Mehlman believes Children's had a lot of explaining to do in 2013, 2008, 2007 and today. (Mehlman pg. 143-144). They should be explaining why they didn't protect the public." (Mehlman pg. 144). Based upon his experience with Dr. Durrani from the

years he worked with him at Children's, Dr. Mehlman's opinion about Dr. Durrani's reputation for truthfulness and honesty in the community is... "he's an unethical sociopath." (Mehlman pg. 178).

430. Dr. Guanciale is employed with the department of orthopedic surgery through University of Cincinnati Physicians. He is also employed by University of Cincinnati Medical Center as "far as my educational role and research role." (Guanciale pg. 11). He's a faculty member in the department of orthopedic surgery. He's an associate professor. He teaches. He teaches residents. He does research. (Guanciale pg. 12). His academic appointment is through the University of Cincinnati. (Guanciale pg. 12). His surgical appointment is through University of Cincinnati Physicians. (Guanciale pg. 12). He never worked for the Health Alliance. He worked for University Orthopedic Consultants of Cincinnati and still had faculty appointment through the University of Cincinnati. (Guanciale pg. 12-13). In 2008, he was director of spine surgery in the orthopedic department. Associate professor. (Guanciale pg. 13). In 2008, he reported to Dr. Peter Stern. (Guanciale pg. 13). In 2008, Dr. Guanciale had privileges at Children's. Dr. Crawford asked him to occasionally assist in some scoliosis surgeries. (Guanciale pg. 14). Dr. Guanciale first met Durrani when Durrani was a resident at University. (Guanciale pg. 15). Durrani was an orthopedic resident. (Guanciale pg. 16)

431. Dr. Guanciale supervised himself, Asghar and Agabegi. The only adult spine surgeons at University. (Guanciale pg. 23). Dr. Guanciale knew Dr. Mehlman and Dr. Wall as faculty members. (Guanciale pg. 28). Dr. Guanciale's business card has UC Health. (Guanciale pg. 78-79). The office manager UC Physicians is Marcella (Guanciale

pg. 79). His private practice was Cincinnati Spine Institute with Dr. Kahn, Dr. Roberts and Dr. Kramer. (Guanciale pg. 81)

432. "Dr. Durrani did surgeries here as well. He even took call here, spine call." (Guanciale pg. 99). This is a reference to University. Dr. Stern did annual reviews for everyone in the department. (Guanciale pg. 112). Dr. Guanciale never contacted anyone at the Health Alliance about Durrani. (Guanciale pg. 137).

433. Dr. Agabegi is a licensed Orthopaedic since 2008. (Agabegi pg. 6). He became board certified in 2010. (Agabegi pg. 7). He was at Children's from August 2008 until March 2009 full time, then part time until 2015. (Agabegi pg. 8-9). He spoke to Dr. Asghar, Guanciale and Stern about his deposition. (Agabegi pg. 9). They have discussed many times over the years. The letters summarize it. (Agabegi pg. 10). Dr. Agabegi had experiences with Dr. Durrani at Children's and UC before Durrani left Children's (Agabegi pg. 12). Dr. Agabegi began his residency in 2002 when Durrani was chief resident. (Agabegi pg. 12). Dr. Agabegi treated Kenny Wilson and Josh Roy. (Agabegi pg. 15). Deters Law clients who had claims with Children's. He's employed by College of Medicine and UC Physicians. Hospitals under UC Health. Agabegi pg. 54). Durrani helped Agabegi get his Children's position. (Agabegi pg. 66).

434. Agabegi left Children's because not enough surgery. (Agabegi pg. 102-103). Dr. Durrani told him Durrani was leaving Children's for the better opportunity of private practice. (Agabegi pg. 135)

435. Dr. Asghar is an employee of UC Physicians. (Asghar pg. 11). He's an assistant professor of Orthopaedic surgery. (Asghar pg. 11). He works out of West Chester. (Asghar pg. 11). West Chester is operated by UC Health. (Asghar pg. 11). Children's and

University have a common resident program. (Asghar pg. 12). They have meetings and research. "Their residency program is what brings us together." (Asghar pg. 12). His first true job in 2005 was at University. (Asghar pg. 19). He was in residency a year or two before Durrani. (Asghar pg. 19¬20)

436. He claims Durrani was not practicing at University of Cincinnati Medical Center. (Asghar pg. 38) Dr. Asghar is mistaken. Durrani was through 2005 through 2008. "Well, UC Medical Center is under UC Health." (Asghar pg. 55). Dr. Asghar admits he did a couple surgeries at Children's. (Asghar pg. 56)

437. Dr. Stern has been on staff at Children's his entire time in Cincinnati. (Stern pg. 18). He does one or two cases a year there. (Stern pg. 18). As Chairman, he has responsibility for the practice of the individuals within the department and the education of the residents that are training at the University of Cincinnati in Orthopaedic surgery. (Stern pg. 24). Durrani was a resident. (Stern pg. 24). Durrani was under Stern during the five years of residency. (Stern pg. 27). Durrani was an average resident. (Stern pg. 44-45).

438. He remembers the formation of the Health Alliance. (Stern pg. 39). He remembers the Health Alliance in 2005 purchased 29 acres for West Chester. (Stern pg. 40). On April 20, 2006, he remembers Christ left the Health Alliance. (Stern pg. 40). He recalls West Chester opened in May 2009. (Stern pg. 40). He knows the University of Cincinnati Physicians, University of Cincinnati Medical Center, the University of Cincinnati joined to form UC Health. (Stern pg. 41). He remembers in June 28, 2012, an affiliation agreement between University of Cincinnati, UC Health and UC Healthcare System. (Stern pg. 41).

439. "I don't think that the department has any responsibility for such concern." (Stern pg. 46). He didn't recall 5 lawsuits against Dr. Durrani during his residency. (Stern pg. 47). At the time Durrani became resident, it was not common to invite foreign medical graduates for interviews. (Stern pg. 48). It was not common to accept foreign medical graduates. (Stern pg. 48). They mostly came from the Midwest. (Stern pg. 49). The program never accepted an applicant from Army Medical College in Pakistan. (Stern pg. 49). American Board of Orthopaedic Surgery in twenty Orthopaedic surgeons involved in certification. (Stern pg. 49). It's stated mission to ensure safe, ethical and effective practice of Orthopaedic surgery for the benefit of the public. (Stern pg. 49). Dr. Stern has been on the Board and been President in 2004 or 2005. (Stern pg. 50)

440. Durrani was Chief Resident from July 1, 2002 until June 30, 2003. (Stern pg. 60) Every resident becomes a chief resident. (Stern pg. 60). On the technical side, I "would say he was average to above average and on the brash side." (Stern pg. 61). Being a Chief Resident is no big deal. (Stern pg. 83-84). Every resident becomes chief resident. (Stern pg. 83-84).

441. Dr. Wall is current director of sports medicine at Children's. (Wall pg. 7). He's been at Children's for 26 years. (Wall pg. 7). In 1993, he was an assistant professor. (Wall pg. 7). In 2005, he became an associate professor. (Wall pg. 7)

442. In 2005, he became division director of orthopedics and he held that position for about five (5) years which would have been the entire time Dr. Durrani was employed at Children's. (Wall pg. 7). He is now, a full professor of orthopedic surgery. All the professorships were and are affiliated with the University of Cincinnati. (Wall pg. 8). At Children's he reports to his division director, James McCarthy. (Wall pg. 8). At

University, he reports to Dr. Michael Archdeacon the director of orthopedics at University of Cincinnati. From 1993 to 2013, he reported to Dr. Peter Stern. (Wall pg. 9).

443. Department meetings at University included physicians in the department of orthopedics at University of Cincinnati and several physician members of the divisions of orthopedics at Children's. (Wall pg. 10). He participated in these meeting from 1993 to 2010. (Wall pg. 11). He believed Dr. Durrani was a good resident at University. (Wall pg. 11). He was partners with Dr. Durrani at Children's from 2005 toward the middle to end of 2008. (Wall pg. 12). He's aware that through UC Department of Orthopedic Surgery he's affiliated with UC Health. (Wall pg. 23). There is an academic affiliation between Children's Orthopedics and University of Cincinnati Orthopedics. (Wall pg. 24). Plaintiff's Exhibit 488 is a 2017 University Orthopedic Newsletter in which Dr. Wall acknowledges he is one of the 12 providers from Children's referenced in the newsletter. (Wall pg. 24). Since 2004, there has been training between residents of Children's and University. (Wall pg. 26). From 2004 to 2009, there was a joint spine fellowship between University and Children's Hospital. (Wall pg. 27). Children's and University have academic research teaching. (Wall pg. 27-28). University residents rotate through Children's. (Wall pg. 29). Children's train residents, but they don't have residents. (Wall pg. 30). The training is affiliated with the University of Cincinnati. (Wall pg. 30)

444. No one at West Chester contacted Dr. Wall to provide information for the credentialing of Dr. Durrani at West Chester. (Wall pg. 114). This is a direct violation of West Chester's credentialing rules which specifically require the department head to weigh in. He provided no information. (Wall pg. 114). If asked, at that time Dr. Wall would not rehire him. (Wall pg. 115). Due to all the issues. (Wall pg. 115). He has no

personal knowledge of West Chester contacting to credential Dr. Durrani. (Wall pg. 115-116)

445. He claims Dr. Stern was part of peer review process, despite Dr. Stern not being employed at Children's. (Wall pg. 119)

446. Dr. Durrani- 80% Children 20% University (Azizkhan pg. 10). Dr. Azizkhan has no recollection anyone from West Chester contacting him in 2008/2009 about Durrani credentialing. (Azizkhan pg. 10). He received the August 7, 2008 resignation letter. (Azizkhan pg. 10-11). He was aware of inhospitable environment. (Azizkhan pg. 12). Letter doesn't say financial issues or Dr. Durrani wanting to own his business. (Azizkhan pg. 12). Jamie Moor was an issue. (Azizkhan pg. 12-13). He has no idea if any Children's personnel were contacted by credentialing for West Chester. (Azizkhan pg. 14)

447. UC Health/Children' s- close collaborations on certain issues. (Azizkhan pg. 15). It was Alliance at the time. (Azizkhan pg. 15). "Children's has an affiliation agreement with the College of Medicine as did the Alliance hospitals at the time." (Azizkhan pg. 15). "There are times we collaborate or certain types of problems, where there are patients who may bridge both institutions." (Azizkhan pg. 15). Logo- University of Cincinnati has been on Children's letterhead. (Azizkhan pg. 16). This is on either Wall's or Durrani's letter to patients after Durrani left. UC College of Medicine sends residents to Children's for their pediatric surgical exposure for three months in their third year and one month in their first year. (Azizkhan pg. 16). "The department of Orthopaedics at the University, as well as the division of pediatric Orthopaedics in—with support from what became UC Health supported a fellowship in pediatric spine surgery." (Azizkhan pg. 16-17). Residents at University do a six-month rotation at Children's. (Azizkhan pg. 18). A

doctor practicing at Children's and UC for six years, UC would know the doctor well. (Azizkhan pg. 19)

448. Dr. Crawford is now employed at UC Health. (Crawford pg. 7). He is Professor Emeritus in Orthopaedic Surgery. (Crawford pg. 7). Clinical practice is part of his Professor Emeritus position. (Crawford pg. 8). "I didn't do adult surgery at all. He did adult surgery. He was part of their triangular fellowship of University, Children's and the Mayfield Clinic." (Crawford pg. 30). He claims to not know Durrani left Children's. (Crawford pg. 33). He claims his conversation with Durrani was merely "I see you're leaving. Yes, I'm leaving." (Crawford pg. 34). This is not believable.

449. Crawford was involved in Durrani coming to Children's. (Crawford pg. 34). "All the medical units in the system are under the University of Cincinnati College of Medicine." (Crawford pg. 40). "All professional roles, all academic roles are given out by the university." (Crawford pg. 40). "I was professor of orthopedic surgery for the University of Cincinnati and director of Orthopaedic surgery for Children's Hospital Medical Center." (Crawford pg. 40). Dr. Crawford performed surgeries at Children's Bethesda, Good Samaritan and University of Cincinnati. (Crawford pg. 42)

450. UC Health/West Chester did not seek his opinion after he left Children's. (Crawford pg. 152). "No. They would've — they would've gotten the chief of the service who would be Eric Wall." (Crawford pg. 152). But they didn't. Dr. Wall did not consult him. (Crawford pg. 152- 153). Christ did not ask. (Crawford pg. 153). At Children's, they were developing a trilogy spine surgery- pediatric- Children's under Crawford. Adult- Mayfield and University under Durrani. (Crawford pg. 153). St. Elizabeth did not reach out to him. (Crawford pg. 154). He doesn't recall if he received

such a form from UC Health or West Chester. (Crawford pg. 155). He gave letters of recommendations for Dr. Durrani over the years. (Crawford pg. 156). UC Health/West Chester did not seek his opinion after Durrani left Children's. (Crawford pg. 152). "No. They would've — they would've gotten the chief of the service who would be Eric Wall." (Crawford pg. 152). But they didn't.

DR. WALL AND CHILDREN'S MANAGEMENT

REGARDING DR. DURRANI (2005-2009)

451. Dr. Mehlman made formal complaints within Children's about Durrani. (Mehlman pg. 36). Dr. Mehlman made complaints to Dr. Wall and "everybody in the room" in the pre-op and post-op conferences. (Mehlman pg. 37-38) This would have included Dr. Crawford. Dr. Mehlman brought issues regarding Dr. Durrani up with Dr. Wall and his partners. (Mehlman pg. 44). Dr. Mehlman believed Dr. Wall's email responses were defensive. (Mehlman pg. 70). Dr. Mehlman brought it to the attention of Dr. Steven Muething, safety officer, too. (Mehlman pg. 74). Dr. Wall did not act forcefully or definitively on Durrani (Mehlman pg. 45). Dr. Mehlman told Dr. Wall "the only thing worse than taking this to Dr. Azizkhan is not to take it to him." (Mehlman pg. 45). Dr. Mehlman did not have direct conversation with Dr. Azizkhan about Durrani. (Mehlman pg. 46). Dr. Wall, Dr. Crawford, Dr. Ray, Dr. Tamai, Dr. Twee Do were at the meetings and heard Dr. Mehlman's concerns. He believes these doctors shared his concerns. (Mehlman pg. 46-47) The TLIF issue was brought to Steve Muething's attention. (Mehlman pg. 52)

452. Dr. Azizkhan was on the Medical Executive Committee at Children's. (Mehlman pg. 84). Dr. Mehlman served on the MEC at Children's a couple years in the late 1990's.

453. Durrani issues were common knowledge. Dr. Mehlman believed it was Dr. Wall, Dr. Rychman and Dr. Azizkhan's responsibility to report to medical board. (Mehlman pg. 197). "Surgeons are expected to be quiet, docile Stepford Wives that come and do surgery and come when they're called, and then move on. So I take exception to the question because it makes it sound like I was weak or somehow not committed to fight to talk to disinterested administrators who were all about corporate protection." (Mehlman pg. 239). Dr. Azizkhan refused to culture a house fly for Dr. Mehlman when the fly landed on an exposed surgical field. (Mehlman pg. 240). Dr. Mehlman saw this as an example of the attitude of management.

454. Dr. Wall told Dr. Mehlman at a pre-op/post-op conference: "Chuck you've been asked to be quiet." This pertained to Dr. Mehlman speaking up about Dr. Durrani. Dr. Mehlman saw this as the low point of his professional career. (Mehlman pg. 164). With emotion, Dr. Mehlman responded: "Eric, the day that I'm quiet in this conference you better check a pulse, because as long as it's my job to teach these residents and these fellows, the next generation of practitioners, how to be ethical and to be evidence-based practitioners, I will continue to speak up." (Mehlman pg. 164-165). This would have been in the 2006-time frame. (Mehlman pg. 165) Dr. Wall was the division director. (Mehlman pg. 165). Dr. Mehlman believes it was a short list of people who would have told Dr. Wall to tell him to shut up: Peter Clayton, Dr. Azizkhan or Dr. Rychman. (Mehlman pg. 166).

455. Alex Taylor became Dr. Mehlman's and Dr. Rohmiller's patient after Dr. Durrani (Mehlman pg. 119) His kyphosis could have been treated non-operatively. (Mehlman pg. 121) He brought it to Dr. Wall's attention. (Mehlman pg. 122) Alex Taylor is a Deters Law client. At one point Dr. Guanciale informed Dr. Wall about Durrani issues. (Guanciale pg. 102). Dr. Wall was informed that the residents were presenting concerns about surgeries being performed by Dr. Durrani's (Guanciale pg. 102). "I had more conversations with Dr. Wall about that as a result." (Guanciale pg. 103). Dr. Guanciale called Dr. Wall from Toronto on the research issue. (Guanciale pg. 142).

456. Dr. Agabegi had conversations with Dr. Wall. (Agabegi pg. 22). He had at least one conversation with Dr. Wall regarding PARS fracture. (Agabegi pg. 22). With respect to Dr. Wall, "I remember in one conversation that I directly had with him that he was concerned and frustrated. (Agabegi pg. 38). Dr. Agabegi did not have any conversations directly with Dr. Azizkhan. (Agabegi pg. 38). Prior to 2009, Dr. Agabegi had discussions "primarily with Dr. Mehlman and Dr. Wall on a limited basis." (Agabegi pg. 44). Dr. Wall expressed frustration about the alleged external review. (Agabegi pg. 114). Dr. Wall was aware of the Durrani issues. (Agabegi pg. 142). Dr. Agabegi had a couple of conversations with Dr. Wall. (Agabegi pg. 142). He spoke to Dr. Mehlman and Dr. Wall about Durrani. (Asghar pg. 24). Doctors at Children's talking about Durrani problems were Dr. Wall, Dr. Mehlman and Dr. Agabegi. (Asghar pg. 39). Dr. Wall and Dr. Mehlman conversations were about concerns about surgical indications. (Asghar pg. 103-104).

457. At the 2008 meeting regarding Children's and Dr. Durrani was Dr. Stern, Dr. Agabegi and Dr. Wall who phoned in from New York City. (Stern pg. 15). Dr. Stern

spoke to Dr. Wall and he arranged the Saturday morning meeting in Dr. Azizkhan's office. (Stern pg. 16). "I raised the concern that Dr. Guanciale raised to me in his letter. I believe that I shared the letter with Dr. Azizkhan. I had previously shared the letter with Dr. Wall, and Dr. Azizkhan told me that he would look into matters." (Stern pg. 16). Dr. Wall was the first person Dr. Stern contacted. (Stern pg. 22). Dr. Stern relayed to Dr. Wall what Dr. Guanciale had written. He told him this must be looked into. "He was a little reluctant at first, and I told him that if he didn't look into it, I would contact legal counsel at Children's Hospital and ask them to look into it." (Stern pg. 23). Dr. Wall did not say why he was reluctant. (Stern pg. 23).

458. From 2009 to 2013 Dr. Stern was sure he spoke to others at Children's but "I can't recall specific individuals." (Stern pg. 23). In an October 3, 2008 email, Dr. Stern read as "expressing concerns to Dr. Wall." (Stern pg. 30). "Dr. Mehlman has raised some serious issues here. I believe Dr. Durrani is fully entitled to due process, but also think this apparently aggressive behavior might warrant some type of independent evaluation. I believe as a profession are must exercise some oversight, especially when it involves patient well-being." (Stern pg. 31). Between 2005 and 2008 at the indication conferences at Children's, Dr. Wall acknowledged Dr. Durrani's indications were discussed, as well as, others. (Wall pg. 13-14). He does not recall whether he believed strongly that indications for surgery were not present and the same related to a Dr. Durrani surgery. (Wall pg. 14). Dr. Wall was aware of one research fraud issue. (Wall pg. 59). Dr. Wall denies Dr. Mehlman was raising concerns about Dr. Durrani for years. (Wall pg. 64). This is very hard to believe. Dr. Wall denies ever informing Dr. Mehlman he's been told to be quiet. (Wall pg. 68-69). Dr. Wall denies Dr. Guanciale informing him orthopedic

residents were expressing concerns about surgery indications by Dr. Durrani. (Wall pg. 70) This is a serious credibility issue for Dr. Wall based upon Dr. Guanciale's claim he did. Dr. Mehlman's concerns were not brought to Dr. Azizkhan's attention. (Wall pg. 79 and 80). Toward the end, they debated Durrani more because he did more surgeries. (Wall pg. 106). Dr. Crawford can't remember Dr. Wall ever approaching him about Dr. Durrani's surgical practices. (Crawford pg. 43).

459. Dr. Wall claims not to know who from Children's would handle the NPDB reports. (Wall pg. 108-109). Do you know why Dr. Durrani was able to continue to perform surgeries after his resignation at Children's Hospital Medical Center? "No." (Wall pg. 111). Were you aware that he was continuing to do surgeries? "Yes." (Wall pg. 111). Did you have an issue or problem with that? "Yes." (Wall pg. 111). Dr. Wall's answers to these three questions are incredulous. He doesn't know about Dr. Durrani's suspensions for dictations. (Wall pg. 122-123). This too is hard to believe since he was division director.

460. West Chester/UC Health, their staff and management, and their executive committee, knew Dr. Durrani had issues at Children's before he applied for privileges there in 2009 because they trained him in his residency and Dr. Stern (Mehlman pg. 182). "How could they not know?" (Mehlman pg. 183)

461. Eric Wall made a comment about you can find a certain amount of sociopaths in every category of humans. He made the comments in direct reference to Dr. Durrani. (Mehlman pg. 179)

THE AUGUST 2008 CHILDREN'S MEETING

LEADING TO DR. DURRANI'S DEPARTURE

462. Dr. Mehlman believes Durrani resigned within several days of the meeting referenced in the October 20, 2009 letter. (Mehlman pg. 137). Dr. Mehlman did not know Durrani resigned and kept working at Children's. (Mehlman pg. 152). Dr. Guanciale had the impression Dr. Durrani was asked to resign. (Guanciale pg. 40). "And based on that letter I felt that I needed to- in my capacity as chair, I needed to discuss his concerns with the individuals at the Children's Hospital Medical Center." (Stern pg. 22). Legal counsel from Children's Hospital had reviewed Dr. Durrani's activities during his time at the Children's and Dr. Durrani resigned. That was within ten days of the meeting. (Stern pg. 17). At the time, Dr. Stern was Chairman of the Department of Orthopaedic Surgery at University of Cincinnati Medical Center (Stern pg. 18). Dr. Stern believes Durrani's resignation came from the meeting. (Stern pg. 18).

463. Dr. Wall had conversations with Dr. Durrani in July 2008. (Wall pg. 53). The conversations were about personnel issues, research data and surgical indications. (Wall pg. 53). Dr. Wall called Jamie Moor a "serious inappropriate sexual relationship." (Wall pg. 54). "It was brought to my attention by Dr. Durrani's wife." (Wall pg. 55). The Moor situation was addressed through HR, but never got resolved. An action plan was set up, but Dr. Durrani did not comply. (Wall pg. 56). Dr. Durrani's HR problems were becoming an issue with his employment because it violated policy. (Wall pg. 57).

464. Dr. Stern was involved because he was Dr. Durrani's academic chairman. (Wall pg. 57). At the meeting referenced in the October 20, 2009 letter was Dr. Stern, Dr. Azizkhan and Dr. Wall (Wall pg. 59). The topics included were the sexual relationship and the research fraud Dr. Guanciale referenced. (Wall pg. 59). Dr. Guanciale was the instigator on the surgical indications issue. (Wall pg. 60). It related to something new

and spondylolysis. (Wall pg. 60). Dr. Durrani was not doing non-operative treatment others would have recommended and doing more surgeries. (Wall pg. 61). Dr. Wall admits the serious concerns raised by Dr. Guanciale about Dr. Durrani led to the meeting with Wall, Stern and Azizkhan. (Wall pg. 62). Surgical indications and exhausting non-operative means were discussed at the meeting. (Wall pg. 62-63).

465. Dr. Wall claims he left the meeting believing Dr. Durrani was not doing surgeries that were contraindicated. (Wall pg. 63). He believed after the meeting Dr. Durrani was still practicing within the standard of care. (Wall pg. 63). However, the meeting did raise serious concerns with Dr. Wall. (Wall pg. 64). "Other than talking to peer review individuals or quality assurance, did you take that information to any other employee at Children's Hospital?" "I don't believe so." (Wall pg. 65). Or to no other physician in the greater orthopedic surgery community. (Wall pg. 65).

466. Dr. Durrani was unhappy at Children's. (Wall pg. 66). Dr. Durrani was unhappy about the affair issue and believed he was underpaid for the amount of his productivity. (Wall pg. 66-67).

467. Toward the end, they debated Durrani more because he did more surgeries. (Wall pg. 106). Dr. Wall doesn't know if Durrani had not resigned whether or not he would have been terminated. (Wall pg. 106-107). Dr. Wall, from HR issues, the research issues, he did not want Dr. Durrani in the department anymore. (Wall pg. 112). This is an unexpected and critical admission. "I didn't want to be taking care of him." (Wall pg. 112). He admits surgical issues were part of it too. (Wall pg. 112). "I would say it was all of the issues." Dr. Wall has no regrets how he handled Dr. Durrani at Children's. (Wall pg. 122). Side shows, affairs, problems, why not rehire. Nothing to do with his

skill and competence as a surgeon. (Wall pg. 126). Dr. Wall hides behind peer review on substantiation of complaints. (Wall pg. 127).

468. At the 2008 meeting regarding Dr. Durrani and Children's, was Dr. Stern, Dr. Agabegi and Dr. Wall who phoned in from New York City. (Stern pg. 15). Dr. Stern spoke to Dr. Wall and he arranged the Saturday morning meeting in Dr. Azizkhan's office. (Stern pg. 16). "I raised the concern that Dr. Guanciale raised to me in his letter. I believe that I shared the letter with Dr. Azizkhan. I had previously shared the letter with Dr. Wall, and Dr. Azizkhan told me that he would look into matters." (Stern pg. 16). Dr. Wall was the first person Dr. Stern contacted. (Stern pg. 22). He relayed to Dr. Wall what Dr. Guanciale had written. Dr. Stern told him this must be looked into. "He was a little reluctant at first, and I told him that if he didn't look into it, I would contact legal counsel at Children's Hospital and ask them to look into it." (Stern pg. 23). Dr. Wall did not say why he was reluctant. (Stern pg. 23).

469. After Durrani's resignation, Dr. Stern saw Dr. Durrani at a social function. They never spoke about the issues. (Stern pg. 20). "I don't believe I ever spoke with him about the concerns." (Stern pg. 21)

THE OCTOBER 20, 2009 AND APRIL 19, 2011

LETTERS TO OHIO MEDICAL BOARD

470. Dr. Mehlman testified that during board collections period an orthopedic is extra careful. Dr. Mehlman noticed in Dr. Durrani an aggressive pattern even during board collections. After he cleared boards, it was "even more striking." (Mehlman pg. 33). By aggressive, Dr. Mehlman meant "stuff that I had never seen before." (Mehlman pg. 33). Dr. Mehlman evaluates surgeons and educates surgeons on what standards of care are.

(Mehlman pg. 35). Children's has a very intense and academic experience. Thirty to forty plus fellows come from around the country. They have organized educational conferences where cases are presented and discussed. There is a lot of transparency. (Mehlman pg. 36). According to Dr. Mehlman, disciplinary action can be taken against a physician under the bylaws outside the peer review process. (Mehlman pg. 146). "One of the most horrible cases is one of the very last patients who suffered permanent paralysis at our hospital." (Mehlman pg. 153).

471. Dr. Mehlman is on the editorial board of the Journal of Pediatric Orthopedics. (Mehlman pg. 150). A review of 600 Dr. Durrani surgeries by a board-certified orthopedic spine surgeon would be the same as an external review. (Mehlman pg. 183). Our expert, Dr. Keith Wilkey has done this. "The principle was that I saw behavior and support offered to him that was striking. People like Peter Clayton, Sandy Singleton and other business decision-makers built a machine around him. We never had spine nurses like we did until Durrani was there. We never had schedulers, that I know of, that hung out in the –in clinic just to schedule the cases as they rolled out, and I sure as heck never saw a surgeon have two ORs three days a week." (Mehlman pg. 208-209).

472. In 2008, Sandy Singleton and Beth Stautberg, tried to help Durrani get his permanent U.S. residency. (Mehlman pg. 173). In 2005, Dr. Mehlman doesn't know if Children's knew Durrani was doing fraudulent surgeries. (Mehlman pg. 180-181). He does believe in 2006, 2007 and 2008 the administration did know. (Mehlman pg. 181). Sandy Singleton, business director, was quite pleased about the money rolling in from Dr. Durrani. (Mehlman pg. 168). She received prominent gifts from Dr. Durrani, including a fur coat. (Mehlman pg. 168). Children's told Dr. Mehlman, other doctors and nurses, not

to talk about Dr. Durrani. (Mehlman pg. 167) It was like "He whose name we shall not say." (Mehlman pg. 167). For a while, third party carriers were not paying for BMP-2. (Mehlman pg. 166).

473. Dr. Mehlman refused to sign Dr. Durrani's permanent U.S. residency papers given to him by Sandy Singleton. (Mehlman pg. 174). Dr. Mehlman may have been suspended once for late records. (Mehlman pg. 170). Dr. Mehlman believed Dr. Azizkhan was "incompetent." (Mehlman pg. 156) "He was a punitive vindictive administrator." (Mehlman pg. 156). When Dr. Azizkhan and Dr. Rychman were fired, there was "jubilation amongst many of my surgical colleagues." (Mehlman pg. 158).

474. Dr. Mehlman did not report to state medical board "because of an atmosphere of fear and retribution within my institution, and a fear for my job and fear for retaliation. (Mehlman pg. 199). Dr. Mehlman did not have the power to report to the NPDB. (Mehlman pg. 200). UC lawyers told them not to send the letter. (Mehlman pg. 220). "I told him then I was sad that I was unable to sign on to it at that time because of the environment that I worked within." (Mehlman pg. 230). Dr. Mehlman worked in a punitive, vindictive environment where he feared for his job. His "chief of surgery was no longer agreeing to participate in the process across the street." "We were not supported by Azizkhan." (Mehlman pg. 230). Dr. Mehlman was not aware of anonymous reporting to Ohio Medical Board. (Mehlman pg. 230). Dr. Mehlman believes University has power over Dr. Agabegi and Dr. Asghar's remarks about University doing all they could. (Mehlman pg. 232).

475. Dr. Mehlman respects Dr. Crawford. (Mehlman pg. 188) But, "he's not perfect." "I think Alvin is a reasonably good judge of character and competence, most of the time."

(Mehlman pg. 189). Obviously not when it came to Dr. Durrani. "Dr. Crawford was in a sad and conflicted position with a young man who was commonly referred to as his son." (Mehlman pg. 211). Mr. Morley from the United Kingdom was the initial Crawford connection to Dr. Durrani. (Mehlman pg. 211). Dr. Mehlman has it "on very good authority that Alvin has been moved to the point of tears has he reflected on his own poor judgment with Dr. Durrani." (Mehlman pg. 212).

476. Dr. Crawford was a regular attendee at conferences. (Mehlman pg. 216). This means Dr. Azizkhan was never at the meetings. (Mehlman pg. 223).

477. Peter Clayton is the former business director over all the surgery at Children's Hospital. (Mehlman pg. 158) Sandy Singleton, division business director. (Mehlman pg. 159). After Durrani was gone a quarter, at an administrative meeting, Peter Clayton asked "What's happened to your spine revenue. There's a big drop off." And I said, "Peter, we're doing only indicated surgery. (Mehlman pg. 159-160).

478. Dr. Durrani had "an incredibly accommodating environment." (Mehlman pg. 138). I never saw another orthopedic surgeon in my entire career get that treatment." (Mehlman pg. 139). Dr. Durrani met with 3 to 4 industry representatives a week. (Mehlman pg. 82). So, when surgeons become the beneficiaries of these companies that are dishing out money, it's been shown clearly to change surgeon behavior." (Mehlman pg. 82).

479. The best review is chart review. (Mehlman pg. 176) If it is not written, it didn't happen. (Mehlman pg. 176).

480. Dr. Mehlman actually contacted the FBI about Durrani anonymously. (Mehlman pg. 231).

481. There is a letter written on April 19, 2011 to the Ohio Medical Board. Signers were Dr. Guanciale, Stern, Kuntz, Asghar and Agabegi (Guanciale pg. 80).

482. No one from Children's ever came to the University conferences." (Guanciale pg. 105). Dr. Durrani was invited to the conference." (Guanciale pg. 104). Dr. Guanciale never spoke to Dr. Durrani about the issues. (Guanciale pg. 109). Dr. Crawford is an excellent surgeon. (Guanciale pg. 114). Eric Wall is an excellent surgeon. (Guanciale pg. 115). "I never considered Dr. Durrani a competitor." (Guanciale pg. 116). We had no review of Durrani's records. (Guanciale pg. 138).

483. Agabegi was told Durrani resigned shortly after the Children's meeting. (Agabegi pg. 25). Concerns were they being viewed as competitors , conflict of interest and not in good faith. (Agabegi pg. 55). It was not "black and white." (Agabegi pg. 55-56). He thinks Dr. Stern told him the external review results. (Agabegi pg. 58). Dr. Joseph reported "alleged" results to Dr. Stern. 1 to 3% of Dr. Agabegi's surgeries had complications. (Agabegi pg. 73). My fellowship was probably 25% pediatric, 75% adult. (Agabegi pg. 75).

484. Dr. Agabegi is unfamiliar with 4731.224 of the Ohio Admin. Code. (Agabegi pg. 94). In 2008, his was a time he was just beginning. (Agabegi pg. 95). Dr. Fegelman was Chairman Surgery West Chester in 2009 (Agabegi pg. 118). Dr. Durrani would not have received the criticism well. (Agabegi pg. 122-123). He did not want to get entangled in the legal battle with Dr. Durrani. (Agabegi pg. 124). Dr. Durrani prior to 2009 was not interested in other opinions. (Agabegi pg. 125). No way to know what course a doctor takes after residency. (Agabegi pg. 129). Mark MacDonald is the lawyer provided by University for him. (Asghar pg. 13).

485. Dr. Asghar only received the letters. (Asghar pg. 14). He did "a lot of thinking and talking to friends and such." before the deposition. (Asghar pg. 14). He spoke to Dr. Agabegi. (Asghar pg. 15). "We talked about how we had a deposition coming up and we discussed the things that had transpired over the past decade. We had talked about the letter, and we talked about events around the time of that letter." (Asghar pg. 16).

486. Dr. Asghar's concerns in 2009 regarding Durrani were regarding the indications for surgery and the appropriateness of surgery. (Asghar pg. 17). Concerns remained the same from 2009 to 2011. (Asghar pg. 17-18). He heard there were other investigations done at other hospitals. (Asghar pg. 26). He thinks West Chester did a review 2011 or 2012. (Asghar pg. 27). In 2013 they formed a committee at West Chester to review his practice. Dr. Joseph, CEO was involved. (Asghar pg. 29). This of course was after 150 lawsuits.

487. Multiple physicians were on the committee. (Asghar pg. 30). The findings were that he had failed to disclose that he had pending legal issues on his recredentialing application. (Asghar pg. 30). "I'm sure there were other things." (Asghar pg. 30). He thought Durrani was technically capable. (Asghar pg. 31)

488. The letter never got signed. (Asghar pg. 32). There were concerns (Asghar pg. 32-33):

Letter from director of spine?

Department of Orthopaedics?

University Medical?

Under academic appointments?

Formal Letterhead?

Private Citizens/Home Address?

Whether it would accomplish anything?

Whether hold water?

Durrani shoot holes?

489. UC Counsel (Asghar pg. 33). In not those many words, were they told UC would not stand behind them if Durrani sued. (Asghar pg. 33-34). There were "things in that letter I cannot personally testify to, but I was—I had concerns. So, I was willing to put my name on there as well, but we all contributed to it." (Asghar pg. 34).

490. In 2009, Dr. Asghar was on the MEC at University Cincinnati Medical Committee. (Asghar pg. 37). Pertaining to the April 2011 letter. UC administration "expressed concerns and we were supported in our concerns." (Asghar pg. 44). He's covering for his current employer. There were concerns how it would be received. Durrani would claim they were competitors. Durrani would claim conflict of interest and bad faith. (Asghar pg. 44-45). Other than complications and code section, he agrees with everything in letter is true. (Asghar pg. 46). He heard regarding Children's meeting "research irregularities," "personal relationship with staff member," "someone had reported him to the board," "the board said they were going to investigate him." "If you investigate me, I'm going to resign." They said "We have to investigate you" and so he resigned. (Asghar pg. 48). "But that was before any formal investigation was ever launched, so nothing ever got reported to NPDB." (Asghar pg. 48).

491. UC counsel was present at the Dean's meeting. (Asghar pg. 48). He doesn't know if it was Dr. Boat. (Asghar pg. 49). He claims University of Cincinnati Medical Center indicated a willingness to take action besides the one 150 case study. (Asghar pg.

49). "I believe internal investigations were performed." (Asghar pg. 51). He does not know so. "The results were such that there was enough concern to require an outside investigation. The concern was that anyone doing an internal investigation was conflicted because we were competitors of his." (Asghar pg. 51). TGL on the letter was Terri Lyons, Angelo Colosimo's administrative assistant. (Asghar pg. 52-53).

492. Other spine doctors in the community were spoken to. (Asghar pg. 52). When asked, Dr. Rohmiller said UC said they would not stand behind them if Durrani was sued, Dr. Asghar would not answer. (Asghar pg. 53)

493. Q: "Is there any – any doubt in your mind that West Chester Health knew about the issues that you were raising in your 2009 letter in or around that time?" A: "They knew because we were raising issues to them." (Asghar pg. 54-55). Dr. Asghar would later try to change this by errata. On paper is not the only knowledge. He practiced at West Chester from the outset. (Asghar pg. 57). From 2012 to 2013, he's been on West Chester MEC. (Asghar pg. 58). "I was on at the time that he left. (Asghar pg. 58). "Prior to his indictment there wasn't any conversation at MEC about him. It wasn't until his indictment that it became the subject of conversation." (Asghar pg. 59). It proves they were "deaf, dumb and blind" or ignored for the money. "This was not a subject of conversation at the MEC level. MEC deals with multiple things ranging from golf outing and – and policies for consults and such, and we doing all of that, and any disciplinary action against a doctor gets brought up to the MEC, if there is one. And that was – that happened after the indictment." (Asghar pg. 59-60). MEC rules cover more than golf outings.

494. Dr. Asghar thinks UC Health West Chester was "in a difficult situation" because their take on it was that other surgeons are complaining about another doctor." (Asghar pg. 65). Durrani defended himself by saying I'm taking care of people no one will. (Asghar pg. 66). He said Kevin Joseph had knowledge about Durrani. (Asghar pg. 66). "The MEC only gets what certain things that are on the roster for the conversation of that evening." (Asghar pg. 66). "There would have been, potentially maybe, before I was on MEC, some discussions about him, but it's not like Durrani comes up every month that we meet at MEC." (Asghar pg. 67).

495. Discussions with spine surgeons included surgeons at Children's. (Asghar pg. 67). He was not at Children's meeting. (Asghar pg. 103). He "had mixed feelings about it" regarding the alleged UC Health external investigation. (Asghar pg. 104) "I think people put together an effort, people who didn't have to, they put a lot of time into it. Yet, we didn't really get anywhere, so I was frustrated by that." (Asghar pg. 104-105)

496. Dr. Asghar was the first surgeon at West Chester. (Asghar pg. 109). Half his practice is there now. (Asghar pg. 109). There is no pre-operative review at West Chester. (Asghar pg. 109). He doesn't practice at Good Samaritan Hospital. (Asghar pg. 111). UC Health did not revoke Durrani's privileges until 2013. (Asghar pg. 116). Within a couple years (so 2005 or earlier) he realized that Dr. Durrani was such a good resource to practice. (Asghar pg. 117). Dr. Durrani would not accept advice or criticism. (Asghar pg. 118). There were happy Durrani patients. (Asghar pg. 118). There were unhappy Durrani patients. (Asghar pg. 118-119). Chunduri said there was a review. (Asghar pg. 121). They were worried about good faith and a claim they chased him out of UC. (Asghar pg. 124).

497. Dr. Stern claims he saw October 20, 2009 letter for the first time ten days before his deposition. (Stern pg. 9). He agrees with each paragraph. (Stern pg. 9-12). He doesn't know if Dr. Azizkhan got back to him. He thinks so. (Stern pg. 17). The April 19, 2011 letter was never sent. (Stern pg. 28). The letter was never sent because: "Dr. Kuntz, who worked for Mayfield, was—my understanding was – was asked not to sign the letter." (Stern pg. 28).

498. "We had spoke with Kevin Joseph, who was the CEO of the West Chester Medical Center, and he promised us to do an independent peer review investigation." (Stern pg. 28). "And finally, quite frankly, we were concerned about potential retribution as Dr. Durrani was assumed to have fairly deep pockets." (Stern pg. 28-29). Dr. Joseph claimed he did an independent review form Boston and "said the review was essentially clean." (Stern pg. 29). It allayed concerns, but not completely. (Stern pg. 29). Best case review is chart review. (Stern pg. 50). He can't recall ever telling Dr. Colosimo in a private meeting in 2013 that UC Health knew all about Durrani but "they" needed money. (Stern pg. 51). Dr. Stern and Dr. Colosimo operated on the same day on Fridays so it's certainly possible they had conversations about Durrani. (Stern pg. 51). Dr. Stern spoke to Dr. Joseph. (Stern pg. 52). He can't recall if Dr. Joseph mentioned how important Durrani was to West Chester financially. (Stern pg. 52). Dr. Stern admits you don't need a statute to report a physician conducting unethical practice or inappropriate practice and harming individuals. (Stern pg. 60).

499. Durrani was "curious." (Stern pg. 61). His "ability to learn" was satisfactory. (Stern pg. 62). He had no problem with Durrani's "research skills." (Stern pg. 62). He's known Dr. Crawford for 40 years. (Stern pg. 64). He did not know Dr. Azizkhan very

well. (Stern pg. 64). He believes Dr. Azizkhan had an excellent reputation. (Stern pg. 64). Durrani's four fellowships were Children's, Texas Scottish Rite, Bill Enneking-Gainsville and Leatherman Group (Stern pg. 65). Durrani's counsel tries to claims Beacon, Mayfield Clinic, neurosurgeons, Asghar, Guanciale, Agabegi, Roberts were not happy Durrani was doing adult spine as competitors. (Stern pg. 66).

500. Durrani's counsel claims Kahn, Tobler, Kuntz were competitors. (Stern pg. 66-67). Dr. Stern said, "there's plenty of work to go around." (Stern pg. 67). Dr. Stern never spoke to Durrani "certainly one could find fault with that." (Stern pg. 68). All the information he received were from other spine surgeons. (Stern pg. 69).

501. "I only know that Dr. Durrani resigned very shortly after that meeting." (Stern pg. 74). "It was quite precipitous." (Stern pg. 74). These allegations against a peer is pretty serious. (Stern pg. 76). Asked about alleged 2011 external review. "It helped allay some concerns." (Stern pg. 82). The alleged external review did not completely satisfy his concerns. (Stern pg. 83). "I had continued concerns." (Stern pg. 83). He feared retribution from Durrani. (Stern pg. 84).

502. He was unaware of Bolan Medical College issue. (Stern pg. 84). Dr. Stern has no independent knowledge Dr. Durrani every graduated from Army Medical College. (Stern pg. 84). He's never reviewed Durrani's Medical Board file. (Stern pg. 85). He's never checked out his resume. (Stern pg. 85). It would not surprise Dr. Stern to find out at least 50 different items on his resume were not truthful. (Stern pg. 85). Dr. Durrani did not have a reputation for truthfulness and honesty in his practice in the Greater Cincinnati area. (Stern pg. 85). He was not aware of the 1998 Scoliosis Research Society issue. (Stern pg. 85-86). Had he known "the decision to accept him into residency would've

been very questionable." (Stern pg. 86). He disagrees on attacks on spine doctors on competitive advantage. (Stern pg. 86).

503. The letter signers have reputations of truthfulness and honesty. (Stern pg. 87). "I believe I would've been happier doing more. (Stern pg. 87). Dr. Mehlman was not an adult spine competitor." (Stern pg. 88). He agrees a board certified Orthopaedic spine surgeon be qualified in your opinion to review Dr. Durrani's patient charts. (Stern pg. 88). He had no issue with Dr. Kuntz's integrity. (Stern pg. 88-89). "Dr. Asghar, Dr. Agabegi and Dr. Kuntz were above reproach." (Stern pg. 89).

504. You never know what course a resident takes. (Stern pg. 89). "I believe sometime during the first two to three years at Children's his reputation became increasingly tarnished." (Stern pg. 90).

505. Why was the letter not sent? Concern of retribution. Concerns Dr. Kuntz not sign. Dr. Durrani bragged about his wealth. (Stern pg. 94)

CHRIST AND GOOD SAMARITAN HOSPITALS

506. Dr. Durrani had a special Christ surgery day and a special Christ outpatient clinic day (Mehlman pg. 154). There is an email July 22, 2005 referencing this being set up.

507. Dr. Guanciale had knowledge Durrani operated at Christ, Bethesda North and Deaconess. (Guanciale pg. 42).

508. "Dr. Guanciale worked at Christ Hospital fairly routinely and he knew two deaths that occurred at Christ Hospital" (Guanciale pg. 125) (Guanciale pg. 126) (Guanciale pg. 127) and they were Dr. Durrani patients. Dr. Guanciale was in private practice operating at the Mercy Health System and Christ. (Guanciale pg. 128). Dr. Guanciale scrubbed in on a Durrani case at Christ. (Guanciale pg. 19).

509. As a resident, Dr. Agabegi did one surgery with Durrani at Christ. (Agabegi pg. 70). It was his first week. (Agabegi pg. 70). Both he and Dr. Agabegi did this at Christ early 2000's and both backed out of the surgeries.

510. Dr. Chunduri told Dr. Asghar there was a Good Samaritan investigation. (Asghar pg. 112). Dr. Asghar scrubbed into five surgeries at Christ.

511. Dr. Stern has been at the medical center since 1979. (Stern pg. 8). In 2009, Dr. Guanciale, Dr. Asghar, Dr. Agabegi, Dr. Roberts, Dr. Kahn and Dr. Burger all spoke to him about Dr. Durrani. (Stern pg. 12-13). Roberts and Kahn were at Christ. (Stern pg. 12). Burger was at Good Sam. (Stern pg. 13).

512. Dr. Wall knew Dr. Durrani from 2004-2009 had a Christ adult spine practice but did not know he had one for University. (Wall pg. 116).

513. "He had a serious complication." He "ended up resigning from Christ." (Asghar pg. 28). He believes Dr. Durrani had a serious complication at Good Sam and an investigation. (Asghar pg. 28). He does not know the result of the investigation. (Asghar pg. 29). He is not aware of any other hospitals in the 2009 time frame through 2013 that conducted investigations. (Asghar pg. 29)

DR. ERIC WALL - CHILDREN'S ORTHOPAEDIC

DIVISION DIRECTOR (2005-2009)

514. Dr. Wall has served on committees at Children's between 2005 and 2008, he doesn't know if one was peer review. He knows he's reviewed cases at Children's. He doesn't know the names. (Wall pg. 17). He has been involved in root cause analysis committees so he believes he has been involved in peer review committees. (Wall pg. 18). Root cause analysis means if there's a serious safety event they will look at what the

root cause of the permanent injury. (Wall pg. 19). He has served on a quality assurance committee. (Wall pg. 19). In the early 1990's, he served on the Medical Executive Committee. (Wall pg. 19). MEC was a monthly meeting in which they discussed how the hospital is doing and various issues. There were subcommittees. (Wall pg. 19-20). He's never served on a credentialing committee. (Wall pg. 20). He has participated in the credentialing of physicians for Children's. (Wall pg.20).

515. Dr. Wall has written letters of support. (Wall pg. 20). Chain of command is he has division director, then Dr. Azizkhan, surgeon in chief, then CEO or other executive. (Wall pg. 35). 2005 to 2008 partners would be Dr. Durrani, Dr. Crawford, Dr. Wall, Dr. Mehlman, Dr. Tamai, Dr. Do and maybe Dr. Von Stein. (Wall pg. 35-36). Children's tracked orthopedic surgeon revenues. (Wall pg. 37). It was on a printout. (Wall pg. 38). It was a spreadsheet. Ten columns. Billings. Collections. (Wall pg. 38).

516. Dr. Wall now does less spine. (Wall pg. 39-40). He's board certified by the American Board of Orthopaedic Surgery. (Wall pg. 40). Between 2005 and 2008, 25% percent of his work was spine. (Wall pg. 40). He did his residency at University of California San Diego. (Wall pg. 40). He did a fellowship at University of California San Diego in spine biomechanics and one at Children's Hospital Los Angeles in pediatrician orthopedics as part of USC. (Wall pg. 41). He's licensed in Ohio since 1993 and also California. (Wall pg. 41). He saw nothing in Dr. Crawford's deposition of importance. (Wall pg. 42). He disagreed with most of the things in Dr. Mehlman's deposition (Wall pg. 42-43). "Some of the events were true, but I think it's more of Dr. Mehlman's opinions of the events, where—where for the—a different reality than I experienced." (Wall pg. 43).

517. He had not read the October 20, 2009 letter. He's known Dr. Guanciale since the 1990's, Dr. Asghar in the 2000's and Dr. Agabegi when he was at Children's too. (Wall pg. 44-46). He disagrees with Dr. Guanciale that Dr. Durrani displayed a pattern of surgical indications that would by most standards appear to be inappropriate. (Wall pg. 49-50).

518. Dr. Wall plays word games. The letter references Dr. Durrani "recommended" fusion on teenagers with back pain. Dr. Wall says it's recommended, it doesn't say he did these things. (Wall pg. 50). Dr. Wall did less than five surgeries with Dr. Durrani. (Wall pg. 51). He denies knowing about the letter references to under 18 patients having artificial disc replacements for pain. (Wall pg. 51-52). He denies knowing the letter's statement that Durrani recommended fusions with normal radiology. (Wall pg. 52). Dr. Wall did not witness the Peter Clayton and Dr. Mehlman exchange regarding spine revenues being down. (Wall pg. 68).

519. Dr. Wall has read the April 19, 2011 letter. (Wall pg. 71). Plaintiff's Exhibit 461 is an email from Dr. Mehlman to Dr. Wall dated November 26, 2007. (Wall pg. 73). Dr. Wall did not believe the procedure was experimental. (Wall pg. 74). "I think maybe one person would label it experimental, and that would be Dr. Mehlman." (Wall pg. 74). Dr. Wall believes the percutaneous spinal fusion in a minimal invasive way was innovative. (Wall pg. 75-76). Dr. Wall believes Dr. Mehlman and he were rivals when Dr. Crawford stepped down and Dr. Wall got the director position. (Wall pg. 78). He believes Dr. Mehlman resented it and it changed their relationship. (Wall pg. 78). He thought Dr. Durrani was the same as all surgeons on criticism against him. (Wall pg. 80).

520. Plaintiff's Exhibit 488 is an email from Dr. Mehlman to Dr. Wall (Wall pg. 81). It's regarding pedicle screw instrumentation. (Wall pg. 82) There were no more cases like it. (Wall pg. 84). IMAST stands for International Meeting Spine Techniques (Wall pg. 85). Dr. Wall claims that the IRB at first said Dr. Durrani did not need approval. (Wall pg. 85) and Dr. Mehlman charged Dr. Frenck's mind. (Wall pg. 86). "Dr. Mehlman has a way of complaining about a lot of things." (Wall pg. 88).

521. "That's his reputation, not only in the hospital, but even outside the hospital. I'd say nationally. (Wall pg. 88-89). Dr. Wall doesn't recall whether or not he took the IRB issue to Dr. Azizkhan. (Wall pg. 91). Cassie Kirby was a research coordinator. Lisa Thornbury too. (Wall pg. 93). In 2008, Dr. Wall believed Dr. Durrani to a degree was world renowned and locally too. (Wall pg. 102). "Mehlman only sees one side of an issue often." (Wall pg. 103).

522. Dr. Durrani would claim patients had physical therapy. (Wall pg. 104-105). Dr. Wall claims Dr. Durrani was never average. He did lots of fellowships. He was surgically skilled. He was innovative. More productive than most surgeons. He worked long hours. He had a thriving practice. Leading edge of medicine. (Wall pg. 109-110). Two OR's common. Three would be uncommon. (Wall pg. 110). OR access constant problem for all surgeons. (110-111).

523. Dr. Wall claims he doesn't know why Dr. Azizkhan left the hospital. (Wall pg. 111). Dr. Durrani did more complicated surgeries so more complications. (Wall pg. 112-113). Dr. Wall admits some tough cases are tough because they shouldn't be operated on. (Wall pg. 113). Fred Rychman was a general surgeon who became an administrator.

(Wall pg. 113-114). He doesn't know if Dr. Rychman approved two or three OR's three days a week for Durrani (Wall pg. 114).

524. Dr. Wall admits Dr. Crawford considered Dr. Durrani like one on his children. (Wall pg. 121). He denies Dr. Crawford would protect Durrani. (Wall pg. 122). Dr. Wall has used BMP-2 a few times. (Wall pg. 124). He didn't get the consent of parents. (Wall pg. 124). He would use BMP-2 when there is possible non-union like spina bifida. (Wall pg. 124).

525. Dr. Wall was unaware of complaints from other employees at Children's, nurses, residents, fellows. (Wall pg. 128). Suspended surgeons can't do elective surgeries. (Wall pg. 131) Yet, Dr. Durrani did. Dr. Durrani was suspended to not do surgeries. (Wall pg. 132). If suspended, can't do elective surgeries. (Wall pg. 133)

DR. AZIZKHAN- CHILDREN'S CHIEF OF SURGERY

DURING DURRANI'S YEARS (2005-2009)

526. Dr. Azizkhan was surgeon in chief. (Azizkhan pg. 7). His responsibilities as such he details. (Azizkhan pg. 7-9). Dr. Azizkhan joined the Children's Board in 2000. (Azizkhan pg. 9). Division under his responsibility. 9 faculty. Clinical care ortho. Academic/educational side. He oversees it all. (Azizkhan pg. 9). He's been on the MEC since 1998. (Azizkhan pg. 10).

527. Dr. Azizkhan "pooh poohs" the untimely dictating. (Azizkhan pg. 20). He denies West Chester would have found Durrani patient safety issues. (Azizkhan pg. 22). He denies finding out about lawsuits. (Azizkhan pg. 22-23). Denies BMP-2 issues. (Azizkhan pg. 23). Children's allowed adult practice at Christ because of "his unique

capabilities and training." (Azizkhan pg. 24). Dr. Crawford "retired" from Children's. (Azizkhan pg. 24).

528. From 2004 to 2008, volume of surgeries grew. (Azizkhan pg. 24). From 1998 to 2014, faculty/numbers doubled. (Azizkhan pg. 25-26). Dr. Durrani helped him deal with complicated patients from all over the world. (Azizkhan pg. 26). Dr. Durrani- "He was the highest clinical revenue faculty member in surgery." (Azizkhan pg. 27). This contradicts Dr. Wall. He claims Durrani's privileges suspended only 24 hours. (Azizkhan pg. 28). He denies BMP-2 rejected by insurance. (Azizkhan pg. 28). This is not true. He never saw the letter which went out by Dr. Durrani to his patients on Children's letterhead. It was not approved. (Azizkhan pg. 30). From January 12, 2005 to March 2009, Dr. Durrani performed 645 spinal surgeries at Children's. Dr. Azizkhan doesn't believe it is a big deal. (Azizkhan pg. 31-32). He "pooh poohs" high number of surgeries- 11/16/07 (6), 11/30/07 (11), 12/17/07 (7), 12/19/17 (7), 2/22/08 (8), 2/29/08 (7), 6/6/08 (8), 6/16/08 (8). (Azizkhan pg. 32-35).

529. Dr. Azizkhan worked with Dr. Boat in N.C. (Azizkhan pg. 45). Dr. Azizkhan was voting member of Children's Board. (Azizkhan pg. 46). He sits on the MEC (Azizkhan pg. 54-55). "Every one of the institutions that he trained at felt he was an absolute star." (Azizkhan pg. 60). He was confident, not arrogant. (Azizkhan pg. 60). He was professional, caring and compassionate. (Azizkhan pg. 63). Patients loved him. (Azizkhan pg. 63).

530. Durrani was creative (Azizkhan pg. 64). He was curious. (Azizkhan pg. 66). Extraordinarily skilled. (Azizkhan pg. 68).

531. Matthew Hammer, Deters Law, went through all Durrani lies/credibility with Dr. Azizkhan. Dr. Azizkhan knew nothing. (Azizkhan pg. 69-77).

DR. CRAWFORD- CHILDREN'S ORTHOPAEDIC DIVISION DIRECTOR PRIOR TO 2005 WHEN DURRANI CAME TO CHILDREN'S

532. Since 2013, it was more, but now Dr. Crawford did surgery once or twice a month. (Crawford pg. 8). He's been an Orthopaedic since 1970. (Crawford pg. 9). Dr. Mehlman was his fellow and then joined Children's. (Crawford pg. 10). He found Dr. Mehlman to be honest based upon his interaction with patients, surgery, conferences and writing. "We've done quite a bit of publishing together." This related to Dr. Mehlman. (Crawford pg. 11). "I personally don't know his reputation as a spine surgeon." (Crawford pg. 11). This is a ridiculous comment. He's reviewed nothing but his deposition. (Crawford pg. 14). Dr. Agabegi was a resident under him, honest in his dealings with Dr. Crawford. His reputation he's a good spine surgeon. (Crawford pg. 15). He won't give opinions as to Mehlman because he trained him. (Crawford pg. 16). Dr. Guanciale honest in his interactions. (Crawford pg. 17). To be spine director, Dr. Guanciale has to be good reputation. (Crawford pg. 18). Dr Kuntz honest in his interactions. (Crawford pg. 18). "He's one of the university doctors and they all have a good reputation." (Crawford pg. 18). Dr. Stern is an honest person. (Crawford pg. 20)

533. Dr. Crawford has supervised spine surgeons. (Crawford pg. 23). From 1977 to 2005, he was director of orthopedic department at Children's. (Crawford pg. 24). He was co-director 2005-2008 with Durrani. (Crawford pg. 24-25). Durrani was director of "adult component." (Crawford pg. 25).

534. Crawford left Children's in 2013. (Crawford pg. 25). He's never been a supervisor when allegation of incompetence, fraud or misconduct made by one doctor against another doctor. (Crawford pg. 26). "If that were to occur to me, I would have to say where's the data. Whatever the allegations are." (Crawford pg. 28). Dr. Crawford would take it to the accused, the director of the division and department of surgery head. (Crawford pg. 29). A review of the medical records "would be part of the data that I would be given, hopefully." (Crawford pg. 29). He can't remember Dr. Mehlman making allegations against Dr. Durrani. (Crawford pg. 42). This is not believable. He denies knowing anything about Dr. Mehlman's email allegations. (Crawford pg. 44-45). This too is not believable. "He was at the Wednesday meeting with the entire staff." (Crawford pg. 46). "I've heard of disagreements." (Crawford pg. 50).

535. He spoke to Dr. John Herring at Scottish Rite the night before the deposition and claims Dr. Durrani was not discussed. (Crawford pg. 54-55). "We have not talked about Durrani in maybe 15 years." (Crawford pg. 56). This is not believable. Scottish Rite was a "limited" fellowship. (Crawford pg. 57). Dr. Crawford claims he did not know paper had to be pulled. (Crawford pg. 58). This is not believable. Herring said he told him. Dr. Crawford recommended Durrani for the Scottish Rite fellowship. (Crawford pg. 61). He would have a problem with a spine surgeon who falsified data. (Crawford pg. 61). But not Durrani?

536. He was unaware of October 20, 2009 letter. (Crawford pg. 62-63). He had never heard anything like this before about Dr. Durrani. (Crawford pg. 64). This is not believable.

537. "That's the first of my knowledge of seeing it, and – and no, I don't agree." (Crawford pg. 65). "I have absolutely no idea about anything." (Crawford pg. 67). This is not believable. "It's almost preposterous. I've never seen it and was never aware of it." (Crawford pg. 67). This is not believable. Fusion for back pain in teenager would have to be looked into. (Crawford pg. 68). He kept log of his surgeries. Surgeons do this too. (Crawford pg. 70). He doesn't recall if Durrani was performing more surgeries than other doctors. (Crawford pg. 74). Because he "didn't know of them," Dr. Durrani never discussed with Durrani surgical choices or allegations against him. (Crawford pg. 75). Prior to 2009, Dr. Crawford was not aware about the disproportionate number of severe complications that Durrani's patients experienced, including death and paralysis. (Crawford pg. 75).

538. While working at Children's full time, Crawford claims he did not interact and meet with the other surgeons and other spine surgeons. (Crawford pg. 75). This is not believable. He claims he was clueless. (Crawford pg. 76). This is not believable. He stated: "I have no knowledge of it." Regarding the letter's allegations about Dr. Durrani. (Crawford pg. 78-79). This is not believable.

539. To artificial disc replacement in skeletally immature patients, he says "come on." (Crawford pg. 79). He calls it incredulous. (Crawford pg. 79). Regarding the allegations, "I have absolutely no knowledge of it." (Crawford pg. 80). He admits it's a good thing for physicians to try to protect the community. (Crawford pg. 81-82). He defines incredulous as almost beyond belief. (Crawford pg. 83).

540. Part of his job was to pay attention; assist physicians; share knowledge; help everyone gets better; community children are protected. (Crawford pg. 83-84). Yet, he

was clueless. (Crawford pg. 85-86). "I don't recall this ever being presented in a conference that I attended." (Crawford pg. 86). This is not believable. "Some of the allegations in this letter are very difficult." (Crawford pg. 88). He had no idea about Durrani documentation issues. (Crawford pg. 92-93). He claims to not know Dr. Asghar's comments in July 27, 2013 email to mean. (Crawford pg. 95-96). He's clueless about Dean's meeting. (Crawford pg. 98). "There are allegations about a lot of things that they may not be factual. If they're factual, then I think they do have." (Crawford pg. 100).

541. What one considers experiment, another may consider investigational. (Crawford pg. 102). Dr. Crawford beginning on page 103 goes through animal protocol. He's familiar with IRB. (Crawford pg. 110). The ethics committee is designed to protect patients. (Crawford pg. 111). He thinks Dr. Wall and Dr. Mehlman discussed the spondylolisthesis through the department. (Crawford pg. 113-114). The complication was not reviewing the literature extensively. (Crawford pg. 114). He would not have agreed to moratorium. (Crawford pg. 115)

542. Dr. Twee Do was trained by Anbi Boachiachi in New York. (Crawford pg. 120). Dr. Agabegi was trained by Harry Herkowitz in Michigan. (Crawford pg. 16). Larry Lenke is in St. Louis. (Crawford pg. 122). He knew Dr. Mehlman and Dr. Durrani disagreed on things. (Crawford pg. 130).

543. Crawford was a non-government special employee working on the FDA board. (Crawford pg. 131). "For consenting, you don't go to surgery without informed consent in humans." (Crawford pg. 132). "This letter now would be a laughing stock in the spine

world." Exhibit 467 (Crawford pg. 133). Non-IRB approved human research in conflict of interest would be serious. (Crawford pg. 135).

544. In 2008, Dr. Wall, friend and "fellow person." (Crawford pg. 136). He did not make notes on the letter to him about hiring Durrani (Crawford pg. 145-146). Before hire, I had been a fellowship director. I had been this residency director. (Crawford pg. 148-149). The pay structure was standard operating procedure. (Crawford pg. 149). "I feel completely responsible for him up to the time he left to do his fellowships." (Crawford pg. 156). After fellowships, he's a little bit different in terms of goals and aspirations, but people change. (Crawford pg. 156-157). Money is an issue (Crawford pg. 157). "You're not paying attention. There's not an orthopaedic surgeon in town now that's not hired by some hospital or something now. There's no independent practice in town anymore." (Crawford pg. 158). Dr. Crawford explains his letters for Dr. Durrani.

545. He's had 57 fellows. (Crawford pg. 170). Residents are his children. Closer than children. It hurts when they are accused. You defend them. He defends Durrani. (Crawford pg. 176-177). Children's, UC and UC Health work together. (Crawford pg. 177). "We come under the same academic control." (Crawford pg. 177).

546. Dr. Durrani was the best of the lot. (Crawford pg. 182). Claims they would have checked out Durrani before hire. (Crawford pg. 182). Durrani confident but not arrogant. (Crawford pg. 183). Durrani knew his limitations. (Crawford pg. 183). Bill Enneking father of Orthopaedic Oncology. Deceased. Gainsville. (Crawford pg. 184-185). Spirted debates in conferences. (Crawford pg. 187). Durrani creative. (Crawford pg. 191). Durrani eager to learn. (Crawford pg. 191).

547. He doesn't understand Dr. Mehlman calling Dr. Azizkhan as immensely peripheral. (Crawford pg. 192). To Dr. Mehlman calling Durrani an unethical sociopath- "You're kidding me?" (Crawford pg. 192). "I don't agree with that." (Crawford pg. 193). Not aware of emails. (Crawford pg. 193). Thinks these doctors would have reported unethical Durrani. (Crawford pg. 193-194). Unaware of any compliance problems with Dr. Durrani. (Crawford pg. 200). Only missed Wednesday meetings except he was out of town. (Crawford pg. 200). No recollection. (Crawford pg. 203). He believes Dr. Azizkhan is a competent surgeon. (Crawford pg. 194). Did not know Dr. Mehlman considered Dr. Azizkhan was incompetent. (Crawford pg. 194-195). He did not think Dr. Azizkhan was punitive, vindictive and administrator. (Crawford pg. 195). He believes Mehlman should not have feared retribution. (Crawford pg. 197). When he ran show, people fear of him. (Crawford pg. 198). When Dr. Agabegi came back in 2007 or 2008 from fellowship, "things had changed" about Durrani. (Agabegi pg. 84). "We felt that it should be investigated." (Agabegi pg. 85). Dr. Guanciale is the main author of the letter. (Agabegi pg. 87)

INFUSE/BMP-2

BACKGROUND INFORMATION

548. The Deters Law Firm, P.S.C., represents approximately 500 Plaintiffs in medical malpractice actions against a former Northern Kentucky/Cincinnati-area spine surgeon named Abubakar Atiq Dr. Durrani (Dr. Durrani), his company, Center for Advanced Spine Technologies, Inc. (CAST), and several area hospitals including, but not limited to, West Chester Hospital (WCH), University of Cincinnati Health (UC Health), Cincinnati Children's Hospital Medical Center (CCHMC), Christ Hospital, Deaconess Hospital,

Good Samaritan Hospital and Journey Lite of Cincinnati, LLC (Journey Lite) (collectively Hospitals).

549. Dr. Durrani performed unnecessary, fraudulent, dangerous, and ultimately damaging surgeries on these Plaintiffs while working for and with these Hospitals.

550. The scheme and artifice to defraud that Dr. Durrani devised, executed, and attempted to execute while working for and with the Hospitals included the following patterns and practices:

a. Dr. Durrani persuaded the patient that surgery was the only option, when in fact the patient did not need surgery.

b. Dr. Durrani told the patient that the medical situation was urgent and required immediate surgery. He also falsely told the patient that he/she was at risk of grave injuries without the surgery.

c. Dr. Durrani often told his cervical spine patients that they risked paralysis or that his/her head would fall off if he/she was involved in a car accident, ostensibly because there was almost nothing attaching the head to the patient's body.

d. Dr. Durrani often ordered imaging studies such as x-rays, CT scans, or MRIs for patients but either did not read or ignored the resulting radiology reports.

e. Dr. Durrani often provided his own exaggerated and dire reading of the patient's imaging study that was either inconsistent with or was plainly contradicted by the radiologist's report. At times, Dr. Durrani provided a false reading of the imaging.

f. Dr. Durrani often dictated that he had performed certain physical examinations and procedures on patients that he did not actually perform.

g. Dr. Durrani often ordered a pain injection for a level of the spine that was inconsistent with the pain stated by the patient or with that indicated by the imaging. Dr. Durrani also scheduled patients for surgeries without learning of or waiting for the results of certain pain injections or related therapies.

h. Dr. Durrani often dictated his operative reports or other patient records months after the actual treatment had occurred.

i. Dr. Durrani's operative reports and treatment records contained false statements about the patient's diagnosis, the procedure performed, and the instrumentation used in the procedure.

j. When a patient experienced complications resulting from the surgery, Dr. Durrani at times failed to inform the patient of, or misrepresented the nature of, the complications.

k. All of the above-mentioned actions were done with the knowledge, cooperation, or intentional ignorance of the Hospitals because Dr. Durrani was one of the biggest moneymakers for the Hospitals.

551. In addition to the civil medical malpractice actions against Dr. Durrani, on August 7, 2013, he was indicted by the Federal Government for performing unnecessary surgeries and for defrauding the Medicare and Medicaid programs. Specifically, the ten-count complaint charged Dr. Durrani with health care fraud, in violation of 18 U.S.C. § 1347, and making false statements in health care matters, in violation of 18 U.S.C. § 1035. There was a subsequent superseding indictment adding over 30 counts.

552. Following these criminal indictments, in December of 2013 and prior to the first Plaintiff's trial in these actions, Dr. Durrani fled the United States and returned to

Pakistan. He has not returned to the United States to face allegations of either criminal or civil liability.

553. Among Dr. Durrani's and the Hospitals' professional failings was the use of a synthetic bone-morphogenetic protein called BMP-2, which was marketed under the trade name "Infuse." Dr. Durrani used BMP-2/Infuse in ways that were either not approved by the federal Food and Drug Administration (FDA) or that were specifically contraindicated as noted on the FDA-approved product labeling. The Defendants had full knowledge of this fact.

554. BMP-2/Infuse was, at the time of the surgeries in question, and currently still is manufactured by a company called Medtronic, Inc. (Medtronic).

555. Dr. Durrani predominantly used BMP-2/Infuse on patients at WCH, which is owned by UC Health.

556. It is Plaintiffs' position that this non-FDA-approved use of BMP-2/Infuse was not only negligent, and fraudulent, but criminal based upon the manner in which it was allowed to be used by Dr. Durrani at West Chester, all with the knowledge and full support of the Defendants.

THE PLAYERS REGARDING BMP-2

557. Dr. Durrani is a citizen of the Republic of Pakistan and was a permanent resident of the United States who, from approximately 2005 to 2013, worked as a spine surgeon in and around Cincinnati, Ohio, until he fled the United States to escape civil liability and criminal prosecution.

558. Medtronic is an Irish corporation, with its principal executive office located in Dublin, Ireland, and its operational headquarters located in Minneapolis, Minnesota.

Medtronic is the world's third largest medical device company and manufactures and markets BMP-2/Infuse. Medtronic sales representatives were also present during the experimental surgeries performed on Plaintiffs, who are clients of the Deters Law Firm.

559. CAST was a corporation organized under the laws of Ohio and had business and medical offices in Florence, Kentucky and Evendale, Ohio. CAST was owned, in whole or in part, by Dr. Durrani.

560. Bahler Medical, Inc. is a manufacturer of medical implants and is a corporation located in the state of Ohio.

561. David Rattigan is an Ohio resident and was and is a sales representative for Medtronic. Further, he is affiliated with Bahler Medical, Inc., was involved in many of the transactions involving BMP-2 and was present for the experimental surgeries in which BMP-2 was used.

562. West Chester Hospital, LLC is a corporation organized under the laws of Ohio. It provides medical facilities and billing support to physicians, including Dr. Durrani, in the state of Ohio. WCH is owned by UC Health.

563. UC Health is a private, non-profit corporation organized under the laws of Ohio. It provides medical facilities, management, administrative, ancillary, and billing support to physicians, and it owns WCH.

564. CCHMC is a medical facility in Ohio where Dr. Durrani was an employee until approximately 2008.

WHAT IS BMP-2/INFUSE?

565. The full name of BMP-2 is "Recombinant Human Morphogenetic Protein-2" (also called rhBMP-2). The following definitions apply:

a. Recombinant – Artificially created in a lab;

b. Morphogenetic – Evolutionary development of an organism;

c. Protein – Essential for growth and repair of tissue.

566. Recombinant human protein (rhBMP-2) is currently available for orthopedic usage in the United States.

567. Medtronic manufactured, marketed, sold, and distributed BMP-2 under the trade name "Infuse."

568. BMP-2 has been shown to stimulate the production of bone.

569. Implantation of BMP-2 in a collagen sponge induces new bone formation and can be used for the treatment of bony defects, delayed union, and non-union.

BMP-2 AS A BIOLOGIC

570. BMP-2 is not a device, but instead it is a biologic. *See* July 2009 American Medical Association Article and 2011 Stanford School of Medicine Article.

571. According to the FDA, "[a] 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service Act Sec. 351(i)1." Available at http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.

572. BMP-2 is a Bone-Morphogenetic Protein that is used to promote bone creation and remolding and falls under the definition of a biologic. *See* AMA article ("bone forming

[1] It should be noted that a biologic can also meet the definitions of drug or device. http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm

properties") and Stanford Article. BMP-2 differs from a medical device in that once implanted, it can only be removed days after surgery. If a patient had a complication due to BMP-2 and did not discover this complication until year after surgery, the patient could not have BMP-2 removed to reduce the complication because BMP-2 is so integrated into the patient's bone.

573. A patient has a right to determine what happens to his or her body and the preservation of that right requires that the patient be informed when a bone growth product, that causes irreversible harm, is placed in his or her body.

WHEN IS IT USED?

574. Recombinant human BMPs are used in orthopedic applications such as spinal fusions, non-unions, and oral surgery.

575. The bone graft contains two parts. The first is a solution of human bone growth protein or morphogenetic protein-2. This protein is found in the human body in small dosages and is important for the healing and formation of bones. The protein is genetically engineered to be utilized in the Infuse Bone Graft product, and it is employed for the stimulation of formation and growth in bones.

576. The second part of the bone graft is an absorbable collagen sponge.

577. Both components of the Infuse Bone Graft structure are used to fill the LT-Cage Lumbar Tapered Fusion Device. This chamber is intended to restore the deteriorated disc space to its original height.

578. FDA-approved use for the Infuse Bone Graft product is only for lower back surgery using an anterior lumbar interbody fusion (ALIF), a technique where the operation on the spine is conducted through the abdomen.

579. In addition, the Infuse Bone Graft product must be used in conjunction with Medtronic's LT-Cage. Use of BMP-2 without the LT-Cage is considered an "off-label" use.

CONTRAINDICATIONS OF USE

580. The FDA specifically warns against the use of Infuse in the cervical spine, citing reports of "life-threatening complications."

581. Any use of Infuse other than in lumbar spine surgeries with the LT-Cage is considered "off-label" use

582. Infuse should never be used on the skeletally immature patient, i.e., in patients less than 18 years of age or those with no radiographic evidence of epiphyseal closure.

583. Infuse should never be used in the vicinity of a resected or extant tumor.

584. Infuse should never be used in those patients known to have active infection at the surgical site.

RISKS ASSOCIATED WITH OFF-LABEL USE

585. When used in an off-label manner, patients may experience problems with pregnancy, including but not limited to: complications in fetal development; allergic reactions to titanium, bovine type I collagen, or bone morphogenetic protein–2; infection; the creation or intensification of tumors; liver or kidney disease; lupus or human immunodeficiency virus (HIV/AIDS); problems with radiation, chemotherapy, or steroids if a patient is malignant; paralysis; bowel and/or bladder dysfunctions; sexual disorders, including sterilization and incompetence; respiratory failure; excessive bleeding, and; death.

THE REGULATORY PROCESS

586. The Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., established two separate approval processes for medical devices: Pre–Market Approval (PMA) and Pre–Market Notification.[2]

587. The FDA's PMA process is lengthy and involves extensive investigation by the FDA. The PMA application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20. Frequently, an experimental program under close FDA scrutiny must be successfully completed before FDA approval can be obtained under this process. FDA regulations also require PMA applicants to submit copies of all proposed labeling for the device. 21 C.F.R. § 814.20(b)(10). The FDA approves a PMA application only after extensive review by the agency and an advisory committee composed of outside experts. 21 C.F.R. § 814.40.[3]

588. In contrast, the FDA's Pre–Market Notification process is more abbreviated and involves less FDA oversight. This process requires applicants to submit descriptions of their devices and other information necessary for the agency to determine whether the devices are substantially equivalent. Pre–Market Notification applicants must also submit their proposed labeling. 21 C.F.R. § 807.87. If the FDA determines that a device is substantially equivalent to a device that was on the market prior to the enactment of the MDA in 1976, the applicant is free to market the device.

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2 *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

[3] *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

589. BMP-2 received PMA (PMA number P000058) for the Infuse/BMP-2 Lumbar Tapered Fusion Device, which PMA provided for limited use with specific requirements for its use on individuals. See Medtronic Package Insert.

SCOPE OF THE PMA AND PRODUCT LABELING

590. The PMA for BMP-2 provided that the product may only be used in patients with the following characteristics:

a. Skeletally mature patient, AND

b. At levels L2-S1, AND

c. Confirmed degenerative disc disease (DDD), AND

d. Using only an open anterior or anterior laparoscopic approach, AND[4]

e. Six months of non-operative treatment prior to treatment with the device, AND

f. In combination with the metallic LT-CAGE.[5]

See Medtronic Package Insert, "INDICATIONS."

591. According to Medtronic's package insert for BMP-2/Infuse as well as other industry literature, the following risks are associated with the use of BMP-2/Infuse:

a. Male Sterility

b. Cancer

c. Increased progression of cancer

d. Suffocation of the cervical region

e. Bone fracture

[4] The anterior interbody fusion approach was developed because the risk of non-union (pseudarthrosis) is significantly higher in posterior approaches. The biggest risk factor for fusion surgery is non-union.

[5] Instrumented fusions involve hardware and are more stable fusions with a shorter recovery time than non-instrumented fusions.

f. Bowel/bladder problems

g. Loss of spinal mobility or function

h. Change in mental status

i. Damage to blood vessels and cardiovascular system compromise

j. Excessive bone mass blocking the ability to treat pain

k. Damage to internal organs and connective tissue

l. Death

m. Respiratory problems

n. Disassembly and migration of components

o. Dural tears

p. Ectopic and exuberant bone formation

q. Fetal development complications (birth defects)

r. Foreign body (allergic) reaction

s. Gastrointestinal complications

t. Incisional complications

u. Infection

v. Insufflation complications

w. Neurological system compromise

x. Non-union

y. Delayed union

z. Mal-union

aa. Change in curvature of spine

bb. Retrograde ejaculation

cc. Scars

dd. Tissue and nerve damage

ee. Itching

ff. Pain

gg. Hematoma

hh. Anaphylactic reaction

ii. Elevated erythrocyte sedimentation rate

592. Injury Percentages:

a. Ectopic Bone Growth-63%

b. Inflammatory Neuritis-15%

c. Osteolysis/Subsidence-13%

d. Acute Swelling-7%

e. Retrograde Ejaculation-2%

f. 85% of time, BMP-2 implanted in off-label use

593. Not a single one of these risks in the last two paragraphs were ever explained to a single patient at West Chester by Dr. Durrani.

594. BMP-2 was NOT approved by the FDA for use in the cervical and thoracic spine and BMP-2 was NOT safe or approved for use in children less than 21 years of age. These uses are considered "off-label."

"OFF-LABEL" USE

595. A use of a device is considered "off-label" if it is not approved under the Pre-Market Approval process OR cleared for such use pursuant to 21 U.S.C. § 360c(f) (also known as "the 510k premarket notification process").

596. Infuse can be implanted in an off-label manner in three ways:

a. Approach/position: Any approach other than an anterior approach;

b. Product: Failure to use LT-Cage (or any cage); mixing rhBMP-2 with other grafting products like Allograft or Autograft;

c. Discs: Use on multiple levels or on a level outside of L2-S1.

597. Dr. Durrani and the Hospitals in which he performed surgeries repeatedly used BMP-2 in these non-FDA-approved manners.

THE NON-COMPLIANCE WITH THE REGULATORY PROCESS

598. The PMA 000058 "Conditions of Approval" specifies the following condition: "Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by the FDA … [a] PMA supplement or alternate submission shall comply with applicable requirements under 21 C.F.R. 814.39[.]"

599. 21 C.F.R. 814.39 requires a PMA supplement pursuant to subsection (a)(1) for new indications of use of the device and pursuant to subsection (a)(6) for changes in components.

600. The PMA 000058 "Conditions of Approval" notes the post-marketing reporting requirement imposed by 21 C.F.R. 814.84, particularly "Identification of changes described in 21 C.F.R. 814.39(a)." Medtronic did not comply with this requirement relating to the intended uses and componentry.

601. The FDA can impose post-approval requirements in the PMA pursuant to 21 C.F.R. 814.82, and this fact results in the device being characterized as "restricted" pursuant to 21 U.S.C. § 360j(e) for purposes of 21 U.S.C. § 352(q). Section 352(q) states

that any restricted device that is distributed or offered for sale with false or misleading advertising is "misbranded."

602. "Indications for use" is a necessary part of the PMA application and the "Indications for use" are required to be limited by the application. Any different use is inconsistent with the PMA.

603. A device that fails to meet the requirements of the PMA or 21 C.F.R. 814 is "adulterated" as defined by 21 U.S.C. § 351(f).

604. 21 C.F.R. 801.6 defines a misleading statement related to a DIFFERENT device contained in the label delivered with the device intended to be used will render the device to be used misbranded.

605. Medtronic did not apply for a PMA supplement, as required by the FDA generally and PMA 000058 specifically, for the off-label uses, nor did it provide warnings of the risks known about the off-label uses. All named Defendants in these cases knew about the occurrences of off-label use.

606. The PMA requires an application prior to marketing for new indicated uses by incorporating the federal requirements and explicitly reciting the text of 21 C.F.R. 814.39 and 814.84 and by specifically stating the range of indicated uses on the PMA.

MEDTRONIC

607. In or about 2001, Medtronic began preparing for the launch of two spinal fusion products, PYRAMID and INFUSE (BMP-2), which it projected would enjoy broad application with spinal surgeons and their patients on a nationwide basis.

608. Medtronic anticipated that both products would initially be limited in application.

609. Motivated by greed and a desire to gain competitive advantage in the marketplace, Medtronic began a course of conduct designed to broaden the application of both products by end-users. The course of conduct involved fraud, false statements, material misrepresentation, and deceit for the purpose of broadening the sales of these products beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

610. On or after July 2, 2002, Medtronic received notification that its Pre-Market Approval application for its BMP-2/Infuse bone graft products had been approved by the FDA. However, such approval was limited to the application of the device from the L4 through S1 levels. Further, the approval mandated the conduct of post-approval studies to evaluate the long-term performance of the BMP-2 bone graft and to study the potential side effects and complications such as the promotion of tumors by the bone morphogenetic protein component of BMP-2. Other studies were conducted as well. See "Allegations against Medtronic in the Unsealed Mississippi False Claims Case."

611. Medtronic engaged in a fraudulent course of conduct designed to maximize its revenues from BMP-2, regardless of whether it would eventually be allowed to remain on the market.

612. One of the physicians Medtronic co-opted into its fraudulent scheme was a Thomas A. Zdeblick, M.D. Dr. Zdeblick was an orthopedic surgeon whose invention, the LT-Cage, was the only approved device to act as the delivery vehicle for BMP-2 into the body.

613. Dr. Zdeblick enjoyed a position within the scientific community as a Key Opinion Leader, and he was both a practicing orthopedic surgeon and professor at the University of Wisconsin.

614. In one of Dr. Zdeblick's first attempts to tout his LT-Cage and rhBMP-2, which would become the active ingredient in the ultimate Infuse/BMP-2 product, he encountered some drawbacks to his goal of promoting his and Medtronic's products, which arose from the policy of certain industry journals, including the journal *Spine,* which followed industry standards before printing peer-reviewed material. See article in the journal *Spine,* published in 2000.

615. Not only were the drawbacks related to industry publishing standards, but the National Consumer Health Information and Health Promotion Act of 1976 enacted certain provisions at 42 U.S.C. § 300u, et seq., whereby the Federal Government had entered the field of medical research publication. Such standards promulgated by the Secretary of the predecessor to the U.S. Department of Health and Human Services required that applications for grants and contracts must be subject to "appropriate peer review." See 42 U.S.C. § 300u-1.

616. The drawbacks encountered with the peer-reviewed *Spine* article were as follows:

a. Attribution that the study was "sponsored by Medtronic Sofamor Danek, Inc.;"

b. The study was conducted under FDA regulations, and was "…designed as a prospective, multicenter, nonblinded, randomized, and controlled pilot study;" and

c. It was accompanied by a cautionary comment, or Point of View, which minimized the exuberance and import of the article.

617. In the article, BMP-2 was touted by Zdeblick and the co-authors as the potential realization of a dream of Dr. Marshall Urist, a revered pioneer in the industry and discoverer of BMP, where it closed with the following: "…it is encouraging to note that Marshall Urist's seminal observation made more than 34 years ago may finally come to clinical fruition."

618. In the Point of View, a Dr. John O'Brien of London questioned whether there could be long-term problems associated with the product. He treated Zdeblick's study with caution and pointed out that simple plaster of Paris has achieved the same or similar results more than 50 years prior. He posited that, "perhaps vascularization…fixation procedures are as important as the biochemical composition of the 'filler.'"

619. Vascularization is achieved through removal of the disc material between two vertebral bodies and then the scraping of the surfaces of the vertebral bodies in a fusion procedure; fixation is the process of securing the motion segment through medical hardware. In other, if the alternative proposed by Dr. O'Brien proved to achieve equivalent or better results, Zdeblick and Medtronic's Infuse/BMP-2 products would be useless and unnecessary.

620. Certain efforts would follow in an attempt to alleviate the drawbacks encountered with the 2000 *Spine* journal article.

621. In 2002, Dr. Zdeblick was installed as the sole editor-in-chief of a medical journal known prior to his installation as the *Journal of Spinal Disorders*. Prior to his installation, the journal enjoyed a fourteen-year history under the co-editorship of Dr. Dan Spangler and Dr. Tom Ducker. Once installed, Dr. Zdeblick successfully supplanted Drs. Dan Spengler and Tom Ducker and became the sole editor-in-chief, a position which would

enable him to have greater control and would aid his participation in the fraudulent scheme.

622. During this same time period, Dr. Zdeblick also enjoyed a position on the associate editorial board of the medical journal *Spine*, the leading publication covering all disciplines relating to the spine.

623. In one of Dr. Zdeblick's actions as editor-in-chief, he set about re-purposing the journal in a way that would aid him in the furtherance of the fraudulent scheme through the streamlining of the publication process.

624. In furtherance of the fraudulent scheme, Dr. Zdeblick re-purposed the journal and renamed it the *Journal of Spinal Disorders and Techniques* (JSDT), announcing that the new journal was "entering a new partnership with *Spine*." As part of this partnership, *Spine* would "continue to function as a broad-based scientific journal" tailored to both clinicians and scientists. However, the *Journal of Spinal Disorders and Techniques* would be directed solely to physicians in clinical practice.

625. Dr. Zdeblick's stated goal was "to provide a forum for up-to-date techniques…", and in furtherance of that goal, Dr. Zdeblick announced that his journal would publish Class II or better clinical articles but would "occasionally accept cutting edge articles with less than one-year follow-up." To justify this streamlined process, Dr. Zdeblick claimed as his goal the ability of his journal "to keep up with the fast pace of progress in the treatment of spinal patients."

626. Arm-in-arm with Medtronic and others, Dr. Zdeblick would in short order abuse his position of trust as the editor-in-chief of JSDT.

627. In the October 2002 edition, JSDT published an article entitled, "Anterior Lumbar Interbody Fusion using rhBMP-2 with Tapered Interbody Cages." This article was co-authored by, among others, Curtis A. Dickman, M.D., who was a developer of Medtronic's PYRAMID plate and who has been paid significant sums by Medtronic through royalty agreements, consulting agreements, and education training and speaking agreements.

628. In addition to his interest in the PYRAMID plate, Dr. Dickman had assisted Medtronic in the approval process for Infuse/BMP-2. As part of the pre-approval hearing process, Dr. Dickman and his Barrow Neurological Associates Group of Phoenix, Arizona had submitted a letter to the meeting of the FDA's Orthopedics and Rehabilitation Devices Advisory Panel, which met on January 10, 2002. In that letter, Dr. Dickman represented that "approval of BMP would provide a significant advance for patient outcome and satisfaction following spinal fusion."

629. In the October 2002 issue of JSDT touting the benefits of Infuse/BMP-2, Zdeblick and others failed to disclose their financial ties to Medtronic, though industry standards require such acknowledgement. Not only did Dr. Zdeblick fail to disclose that he profited from each and every surgery which Infuse/BMP-2 was used through rights in the exclusive delivery vehicle, his LT-Cage, but no reference whatsoever to their financial ties to Medtronic was made either by Dr. Zdeblick or Dr. Dickman.

630. For years, the recognized gold standard for spinal bone grafts has been the use of autogenous bone, or bone harvested from the patient's own iliac crest, or hip bone. Medtronic designed to have its Infuse/BMP-2 product supplant autogenous bone as the

gold standard in the medical community, and utilized false statements, a fraudulent enterprise and the support of Federal funds to do so.

631. As part and parcel of Medtronic's fraudulent scheme, the October 2002 study was published in Dr. Zdeblick's journal three months after Medtronic received FDA approval for Infuse. As the article shows, it was actually received on March 28, 2002 or after Dr. Zdeblick had accomplished installment as the editor-in-chief and was accepted by Dr. Zdeblick's journal for publication on July 30, 2002.

632. At the same time Dr. Zdeblick's journal was publishing the initial article on Infuse, Dr. Zdeblick was already finalizing and preparing for subsequent publication a follow-up article to tout Infuse potentially as the new gold standard. A second article, co-authored by Dr. Zdeblick and two other co-authors of the original article, was entitled "Is Infuse Bone Graft Superior to Autograft Bone? An Integrated Analysis of Clinical Trials using the LT-Cage Lumbar Tapered Fusion Device."

633. This second article was published in Vol. 2 of 2003 and once again, there was no mention of Dr. Zdeblick's financial ties to Medtronic.

634. This second article would serve as the second covert advertisement for the Infuse product, and the article states that "the purpose of our analysis was to investigate the potential statistical superiority of Infuse bone graft to autograft…"

635. This second article went on to announce the July 2002 FDA approval of rhBMP-2.

636. This article included as an "acknowledgment" an expression of gratitude to the physicians "who provided patients for this study and to the clinic research group at Medtronic Sofamor Danek for their help in data collection and statistical analyses."

However, the article still failed to advise the medical community that some or all of the authors reaching these conclusions touted as monumental had direct financial interests tied to those conclusions.

637. Rather, the failure to report these clear conflicts of interest on the part of those holding positions of trust both within the medical community and over patients was part of Medtronic's fraudulent enterprise. However, unchecked by appropriate peer review, Medtronic was able to systematically accomplish their goals.

638. In its 2003 Annual Report, and without recognizing that Zdeblick was being paid by Medtronic, Medtronic cited to Zdeblick's 2003 as reporting that Infuse "…may become the new gold standard in spinal fusion surgery."

639. By its 2006 Annual Report, if not earlier, Medtronic had removed all doubt, declaring that after its introduction in 2002, "Infuse Bone Graft quickly became the gold standard for certain types of lumbar fusion."

640. Medtronic's fraudulent scheme was successful and resulted in a revenue stream ranging from 700 to 900 million dollars per year.

641. It has been reported that around the same time these stories about Infuse were published, editors at the Spine Journal began receiving complaints from doctors around the country who were pointing out contradictions between papers published by doctors with financial ties to Medtronic and other data involving Infuse complications.' See *Journal Sentinel* article of John Fauber.

642. Through the use of these sham consulting, royalty and education/training agreements with its physician agents in this fraudulent enterprise, Medtronic has reaped windfalls in the billions of dollars. Medtronic has used this fraudulent enterprise and civil

conspiracy to drive its vast profits and enhance its market position beyond that which it would have realized without engaging willfully, knowingly and potentially deliberate, conscious, or reckless indifference in the fraudulent enterprise and fraudulent concealment. See Mississippi case.

643. Defendants had full knowledge of all these facts pertaining to Medtronics.

FDA PUBLIC HEALTH NOTIFICATION

644. On July 1, 2008 the FDA issued a Public Health Notification entitled "Life-Threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion."

645. This notification was sent to health care practitioners all across the United States warning of the complications associated with BMP-2, specifically when used in the cervical spine.

646. In the notification the FDA stated they received at least 38 reports of complications during the prior four years with the use of BMP-2 in cervical spine fusions.

647. The complications were associated with swelling of the neck and throat areas, which resulted in compression of the airway and/or neurological structures in the neck.

648. Some reports describe difficulty swallowing, breathing or speaking and severe dysphagia following cervical spine fusion using BMP-2 products had also been reported.

649. The notification further stated that, "since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies.

650. The Notification further emphasized the importance of fully informing patients of these potential risks and said that patients treated with BMP-2 in the cervical spine should know:

a. The signs and symptoms of airway complications, including difficulty breathing or swallowing, or swelling of the neck, tongue, mouth, throat and shoulders or upper chest area

b. That they need to seek medical attention immediately at the first sign of an airway complication

c. That they need to be especially watchful 2-14 days after the procedure when airway complications are more likely to occur

d. rhBMP-2 (contained in Infuse Bone Graft) has received pre-market approval for fusion of the lumbar spine in skeletally mature patients with degenerative disc disease at one level from L2-S1 and for healing of acute, open tibial shaft fractures stabilized with an IM nail and treated within 14 days of the initial injury

651. Additionally, BMP is not approved in any manner for use in patients who are skeletally immature (<18 years of age) or pregnant.

652. Dr. Durrani and the Hospitals ignored ALL of these warnings and used BMP-2 in cervical spine surgeries, children, and those with known compromising factors such as osteoporosis, smoking, and diabetes.

653. Furthermore, the Notification stated that the FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices.

654. The Hospitals that allowed Dr. Durrani to use BMP-2 in their facilities failed to report any complications resulting from his use of BMP-2.

SENATE FINANCE COMMITTEE REPORT

655. Medtronic's actions did not go unnoticed, and in June of 2011 the Senate Finance Committee began an investigation into the fraudulent actions of Medtronic.

656. Medtronic produced more than 5,000 documents pertaining to 13 different studies of BMP-2 for the investigation.

657. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) released the results of their 16-month investigation into Medtronic, which revealed questionable ties between the medical technology company and the physician consultants tasked with testing and reviewing Medtronic products.

658. The investigation revealed that Medtronic employees collaborated with physician authors to edit and write segments of published studies on BMP-2/Infuse without publicly disclosing this collaboration.

659. These fraudulently-produced studies may have inaccurately represented BMP-2's risks and may have placed added weight on the side effects of alternative treatments.

660. The Senate investigation further found that Medtronic also maintained significant, previously undisclosed financial ties with physicians who authored studies about BMP-2, making $210 million in payments to physicians over a 15-year period.

661. Senator Baucus stated, "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies

distort the facts the way Medtronic has. Patients everywhere will be better served by a more open, honest system without this kind of collusion."

662. Senator Grassley stated, "The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and the studies they feature. These publications are prestigious and influential, and their standing rests on rigorous science and objectivity. It's in the interest of these journals to take action, and the public will benefit from more transparency and accountability on their part."

663. Major findings of the investigation include:

a. Medtronic was involved in drafting, editing and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's role in authoring or substantially editing these articles was not disclosed in the published articles. Medical journals should ensure that any industry role in drafting articles or contributions to authors is fully disclosed.

b. Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

c. An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with BMP-2/Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

d. Medtronic officials inserted language into studies that promoted BMP-2 as a better technique than an alternative by emphasizing the pain associated with the alternative.

e. Documents indicate that Medtronic prepared one expert's remarks to the FDA advisory panel meeting prior to BMP-2 being approved. At the time, the expert was a private physician but was later hired to be a vice president at Medtronic in 2007.

f. Medtronic documents show the company successfully attempted to adopt weaker safety rules for a clinical trial studying BMP-2 in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

YODA STUDY

664. In response to the various controversies surrounding BMP-2/Infuse, including a June 2011 article in the journal *Spine*, the Yale University Open Data Access (YODA) team reached an agreement for Medtronic to provide full individual participant data from all their trials of rhBMP-2 and allow unrestricted independent re-analysis of this data.

665. The YODA study involved research teams at two universities – the University of York and the Oregon Health and Science University.

666. The review focused exclusively on the use of rhBMP-2 in patients undergoing spinal fusion surgery for treatment of degenerative disc disease, spondylolisthesis, or any other relevant spinal condition.

667. The three main objectives of the study were: 1) to examine the potential benefits of BMP-2, 2) to examine the potential harms of BMP-2, and 3) to assess the reliability of the published evidence base.

668. Medtronic submitted data from 17 studies, including 12 randomized controlled trials (RCTs).

669. In total, the YODA study analyzed the data from 1,409 participants.

670. Though the results showed moderate success with fusions as a result of BMP-2, the study found that BMP-2 results in several different complications including: arthritis, implant-related events, retrograde ejaculation, wound complications, and neurological, urogenital, and vascular events.

671. In regard to the alleged tampering with the peer-reviewed studies by Medtronic, the YODA study found that only two out of twenty peer-reviewed journal publications reported a comprehensive list of all adverse events that occurred during the studies.

672. Furthermore, the way in which adverse event data was presented in the literature was inconsistent, and the rationale for presenting some adverse events but not others was rarely clear.

673. The study concluded that for the period up to 24 months after surgery, treatment with BMP-2 increases the probability of successful fusion (according to Medtronic definitions and reports, which the study noted "were subjective so it is not possible to confirm whether reported successful fusions truly were successful" see YODA Study, p. 35) but this does not translate to clinically meaningful benefits in pain reduction, function, or quality of life. The small benefits in these outcomes observed from six months onward come at the expense of more pain in the immediate post-operative period and a possible increased risk of cancer.

674. Even more relevant to the case against Dr. Durrani and the Hospitals is the YODA study's conclusion that, "[i]t is very important that these findings are expressed clearly and discussed with patients so that they can make informed choices about the type of surgery they would prefer." *Id.*

675. The University of Oregon Study determined that Infuse/BMP-2 is not better than Autograft, while the University of York study determined that Infuse/BMP-2 offers only a slight and not statistically significant advantage over Autograft.

676. The YODA study concluded that Medtronic "misrepresented the effectiveness and harms through selective reporting, duplicate publication, and underreporting."

677. Adverse event categories such as heterotopic bone formation, osteolysis, and radiculitis were not included in participant databases or internal reports; therefore, the safety profile was not fully assessed.

678. The YODA study further concluded that Medtronic was involved in drafting, editing, and shaping the content of medical journal articles on Infuse/BMP-2 authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles.

679. Medtronic paid a total of approximately $210 million to the physician authors of Medtronic-sponsored studies on Infuse from November 1996 through 2010 for consulting, royalty and other arrangements.

680. An email exchange showed that a Medtronic employee recommended against publishing a complete list of adverse events or side effects possibly associated with Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

681. Medtronic officials inserted language into studies that promoted Infuse as a better technique than an alternative procedure by overemphasizing the pain associated with the alternative procedure.

682. Medtronic's actions violated the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. See United States Senate Committee on Finance, October 2012.

683. Infuse was intended for a single level anterior lumbar interbody fusion performed with all three components in a specific spinal region. The three components are a tapered metallic spinal fusion cage (NOT PLASTIC), a recombinant human (BMP) bone Morphogenetic Protein, and a carrier/scaffold for the BMP and resulting bone. The Infuse product is inserted into the LT-CAGE Lumbar tapered Fusion Device component to form the complete Infuse Bone Graft/LT–Cage Lumbar Tapered Fusion Device. These components must be used as a system. The Infuse Bone Graft component must not be uses without the LT-Cage Lumbar Tapered Fusion Device component.

684. BMP-2 is not supposed to be used in minors.

685. BMP-2 is not supposed to be used with smokers and diabetics because of vascular slowing.

686. BMP-2 should not be used with women in child bearing years.

687. BMP-2 is contraindicated for patients with a known hypersensitivity to rhBMP-2 and should not be used in the vicinity of a resected or extant tumor, in patients with active malignancy, or in patients undergoing treatment for a malignancy.

DR. DURRANI AND BMP-2

688. Despite all of these warning signs, Dr. Durrani, with the full knowledge of the Defendants, continued to use BMP-2 in ways not approved by the FDA, or in an "off-label" manner.

689. As early as 2007, Dr. Durrani and UC Health knew there were issues with BMP-2 because insurance companies such as Anthem were refusing to pay for BMP-2.

690. Medtronic provided in writing to Dr. Durrani and CAST the approved uses for Infuse/BMP-2.

691. However, Dr. Durrani and the Defendants continued to use BMP-2 in off-label ways, including but not limited to:

a. Using BMP-2/Infuse in children, despite Medtronic specifically requiring it be used only in "skeletally mature patients;"

b. Using it outside the L2-S1 level of the spine;

c. Ignoring the requirement that BMP-2/Infuse only be used for Grade 1 spondylolisthesis or Grade 1 retrolisthesis;

d. Not requiring at least six months of non-operative treatment prior to the use of BMP-2/Infuse;

e. Using BMP-2/Infuse without the required cage;

f. Not using the "carrier scaffold" in conjunction with BMP-2/Infuse as required;

g. Using BMP-2/Infuse without proper training despite Medtronic's warning, "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience."

692. Dr. Durrani was a paid consultant for Medtronic.

693. According to Dr. Durrani's own deposition testimony in several cases, Medtronic required one of their representatives to be present in the operating room when its product BMP-2/Infuse is used.

694. Because Medtronic representatives were present in these surgeries, Medtronic knew when Dr. Durrani used BMP-2/Infuse outside the approved uses according to Medtronic's own guidelines.

695. Dr. Durrani was encouraged by Medtronic to obtain peer review and published studies from Medtronic sales representatives to support his use of BMP-2/Infuse.

696. Dr. Durrani was encouraged by Medtronic to be an advocate for his patients and describe how BMP-2/Infuse technology can benefit them.

697. When asked how he got his Medtronic grant, Dr. Durrani responded, "You apply to the Medtronic's corporate and say this is what we want to do, like everybody else in the country applies, and then they come and evaluate the thing and say, "Okay, we think it's worthy. We'll give you the grant."

698. In regard to his role as a Medtronic consultant, Dr. Durrani stated, "If there are certain products that they help us in developing, then they will come to us for a certain consultant role for a certain product development."

699. Dr. Durrani also stated, "I was involved in the development of the minimally invasive spine instrumentation."

700. Dr. Durrani gave conflicting reports on his financial relationship with Medtronic.

701. In a deposition, when asked when his relationship with Medtronic began, Dr. Durrani responded "2000-it's 2003, '04. Something in that category. I'm not sure. It's on the Medtronic website. You can go look at it."

702. Medtronic's website has no information regarding their relationship with Dr. Durrani.

703. In another deposition, Dr. Durrani stated he began his relationship with Medtronic in "2005 or '06."

704. Dr. Durrani also gave conflicting reports on how much compensation he received from Medtronic for his consultation services.

705. In one deposition, Dr. Durrani stated in response to an inquiry as to how much payment he received, "It's a standard compensation. Again, it's on the website, how much they've paid us."

706. Again, this information is not available on the Medtronic website.

707. In another deposition, when asked if he received income from Medtronic, Dr. Durrani replied, "No, I don't."

708. When questioned further if he received a fee as a consultant, he stated, "If you do a work, there is a contractual obligation that they have to pay you. As I told you in my last deposition, they did declare it on their website, so you can actually go on the website and see how much they paid."

709. In another deposition, Dr. Durrani stated that he received, "less than $10,000 in ten years" from Medtronic.

710. An email dated July 30, 2008 from Medtronic Senior Product Manager Katie Stamps to Dr. Durrani states that she "is in the process of working on the renewal of your [Dr. Durrani's] consulting agreement." As stated, this information is not available on Medtronic's website, nor is any information relating to Dr. Durrani's role as a consultant for Medtronic.

711. A CCHMC packet relating to its Orthopedics department indicated that Dr. Durrani received $60,000 in grants, contracts, or industry agreements from Medtronic Sofamor Danek in FY 2008.

712. Financial information discovered concerning Dr. Durrani's relationship with Medtronic was found in Dr. Durrani's biography on the website for the Orthopaedic & Spine Institute, which Dr. Durrani currently operates in Pakistan. The biography states that "Dr. Atiq Dr. Durrani has also received the Clinical Spine Fellowship Grant by the Department of Orthopaedic Surgery which was funded by Medtronic Sofamor Danek with a budget of $59,170 per year." See http://www.osi.com.pk/doctor/dr-atiq-Dr. Durrani-md/.

713. When a request was made to Medtronic regarding its affiliation with Dr. Durrani, the Medtronic Supplier Relations Team stated that Dr. Durrani's "name [is] not listed in our system."

714. Medtronic further responded to the Deters Law Firm's request that the firm would need a "Vendor I.D. Number," which neither Medtronic nor any other party has provided.

715. David Rattigan, Dr. Durrani's main Medtronic representative from Bahler Medical, is actively fighting a subpoena to a give a deposition in these cases.

716. David Rattigan and Medtronic have the same lawyer. Despite the Deters Law Firm's willingness to cooperate in scheduling the date for a deposition, they have refused until recently. Mr. Rattigan's deposition is currently scheduled for the month of June 2015.

717. In summary, clients of the Deters Law Firm, with the full knowledge and intentional consent of all Defendants, became unsuspecting experiments for real world

testing of Medtronic hardware and BMP-2, by and through Dr. Durrani and CAST, who had secret financial connections to Medtronic, improper motives, and submitted false claims. The government paid for many of these improper and unregulated experiments as a result of the false claims made by Dr. Durrani, with the knowledge of Medtronic, under the veil of "medically necessary" surgeries.

718. Despite repeated requests, Medtronic has refused to cooperate in providing any requested information and is actively downplaying their connections to Dr. Durrani.

THE DEFENDANTS AND BMP-2

719. The Defendants allowed and encouraged these practices by Dr. Durrani for the sole purpose of money and greed.

720. David Rattigan was always present in Dr. Durrani's operating rooms as a representative of Medtronic.

721. David Rattigan's sole job was to deliver the BMP-2/Infuse to the Hospitals and make sure that it was inserted correctly into the patient.

722. David Rattigan's presence in the OR further supports the Defendants awareness of Dr. Durrani's fraudulent use of BMP-2/Infuse.

723. UC Health Stored BMP-2 at UC Health Business Center warehouse located in Hamilton County.

724. Dennis Robb, the Senior Vice President of Operations and Chief Supply Officer for UC Health[6] spends $369 million annually and 73% of his budget on contracting[7].

[6] Robb Deposition Page 8, Brenda Shell Case
[7] Robb Deposition Page 10

725. Robb was intimately familiar with BMP-2/Infuse and was in charge of acquiring the product for UC Health, which would then keep an inventory of BMP-2/Infuse and supply and distribute it to the Hospitals out of the warehouse as needed.

726. Robb would place an order with Medtronic, Medtronic would deliver BMP-2/ Infuse to the UC Health Business Center warehouse, and Robb would do a three-way match based on what he ordered, what Medtronic delivered, and the price quoted by Medtronic.

727. The BMP-2/Infuse would be distributed to West Chester from the UC Health Business Center warehouse almost on a daily basis (five to six times a week) based on the inventory demand.

728. UC Health clearly was involved in placing BMP-2/Infuse into the stream of commerce by storing, supplying, and distributing BMP-2/Infuse to its hospitals as needed for surgeries.

729. Despite this awareness, the Defendants NEVER obtained its patients' informed consent regarding the experimental and fraudulent use of BMP-2/Infuse.

730. The **WCH Policy and Procedure Manual** states, in part:

Risk Management: Acknowledgment of Informed Consent. Policy:

No examination or treatment may commence without the consent of the patient or the patient's legally authorized representative.

The principle of informed consent is based on the individual's right to privacy and self-determination, which includes the right to make informed, reasoned decisions concerning one's physical and mental well-being.

It is the responsibility of the treating physician to obtain informed consent.

A nurse may witness the signature of the patient on the Acknowledgment of Informed Consent form if the patient verbalizes an understanding of the procedure, risks, benefits, and alternatives, as explained by the physician.

Informed Consent for surgical or medical procedure and sedation:

a. It is the responsibility of the attending physician to obtain informed consent prior to the procedure. The patient, or his/her representative, will be advised by his/her physician of:
b. The explanation of the procedure
c. The benefits of the procedure
d. The potential problems that might occur during recuperation
e. The risks and side effects of the procedure which could include but are not limited to severe blood loss, infection, stroke or death.
f. The benefits, risks and side effect of alternative procedures including the consequences of declining this procedure or any alternative procedures.
g. The likelihood of achieving satisfactory results

The patient's consent must be documented for:

a. Surgical procedures and invasive procedures
b. Medical regimens of substantial risk, or that are the subject of human investigations or research must be in writing and signed and dated by the patient or his/her authorized representative.

731. **WCH/UC Health Policy #ADM.02**, states in part:

a. No examination or treatment may consent without the consent of the patient or the

patient's legally authorized representative.

b. The principle of informed consent is based on the individual's right to privacy and self-determination which includes the right to make informed, reasoned decisions concerning one's physical and mental well-being.

c. It is the responsibility of the treating physician to obtain informed consent.

Informed Consent for Surgical or Medical Procedure and Sedation:

It is the responsibly of the attending physician to obtain informed consent prior to the procedure. The patient, or his/her representative, will be advised by his/her physician of:

a. The explanation of the procedure

b. The benefits of the procedure

c. The potential problems that might occur during recuperation

d. The risks and side effects of the procedure which could include but are not limited to severe blood loss, infection, stroke or death.

e. The benefits, risks and side effect of alternative procedures including the consequences of declining this procedure or any alternative procedures.

f. The likelihood of achieving satisfactory results

Completion of the "Consent to Hospital and Medical Treatment" form to examine and treat is NOT sufficient as consent to perform a surgical procedure, invasive procedure, or for medical regimens of substantial risk or that are the subject of human investigation or research.

732. WCH requires its own written consent because it knows its responsibility. It cannot require its own written consent and then "wash its hands" of the responsibility.

733. The Defendants had the responsibility to carry out these consent rules.

734. Dr. Durrani oftentimes used BMP-2 and/or PureGen “off-label” when performing surgeries.

735. BMP-2 is manufactured, marketed, sold and distributed by Medtronic under the trade name “Infuse.”

736. Dr. Durrani is a consultant for Medtronic.

737. Defendants did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

738. Medtronic, provided in writing to Dr. Durrani and CAST the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

739. BMP-2 is not approved by the Food and Drug Administration for use in the thoracic spine.

740. BMP-2 is neither safe nor approved for use on children less than twenty-one (21) years of age.

741. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion (“ALIF” or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component (“LT-CAGE”)

742. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by

the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

743. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

744. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

745. Dr. Durrani, CAST staff and employees, and West Chester/UC Health personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

746. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

747. Plaintiff was not informed by Defendants that Dr. Durrani used Infuse/BMP-2 in her surgeries.

748. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in her surgeries in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

749. Plaintiff would not have consented to the use of BMP-2 in her body if informed of the risks by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

750. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Infuse/BMP-2's use in her procedures.

751. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

752. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

753. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

754. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

755. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

756. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

PUREGEN NARRATIVE

757. Although Plaintiff did not have PureGen. Plaintiff is providing a PureGen narrative to reflect and relate the overall negligence in the operation of West Chester Hospital.

PUREGEN BACKGROUND

758. PureGen Osteoprogenitor Cell Allograft (PureGen) is a highly concentrated, pure population of Early Lineage Adult (ELA) stem cells that originates in bone marrow and is collected from live, healthy donors.

759. PureGen is harvested from living human beings under the Stem Cell Collection Program administered by the Food and Drug Administration (FDA) and is defined as both a “biologic” by 42 U.S.C. 351(i) and a “drug” as defined by U.S.C. 321(g).

760. PureGen’s purpose was to facilitate bone fusion by mimicking the regenerative environment of youthful tissues by increasing the concentration of stem cells available to

repair tissue and build bone.

761. When used off-label, as Dr. Durrani often did, biologic bone allograft frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord.

762. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

763. Alphatec Spine, Inc. is a corporation under the laws of California, and jointly developed and distributed PureGen in the State of Ohio.

764. Alphatec Holdings, Inc. is a holding corporation formed under the laws of Delaware with no operations separate from the holding of other companies which owns Alphatec Spine, Inc.

765. Dirk Kuyper was President and CEO of Alphatec Holdings, Inc. from February 2007 to August 2012.

766. Parcell Laboratories, LLC is organized under the laws of Delaware and jointly developed PureGen.

767. Alphatec and Parcell co-developed the product "PureGen", and both expected PureGen would be initially limited in application.

768. PureGen is produced and distributed by Alphatec Spine, LLC, a division of Alphatec Holdings.

769. PureGen was entered into 3 clinical trials by Alphatec on or around February 9, 2011 which were scheduled to last until September of 2013.

770. The study population were 50 male/female subjects 18 years and older suffering

from symptoms of cervical degenerative disc disease in one to four contiguous levels between C3 and T1.

771. The clinical trial required:

a. Inclusion

i. Age over 50

ii. Side-by-side use of PureGen and Autologous bone in the same patient for radiographic comparison

iii. Symptomatic lumbar degenerative disc disease in up to 2 contiguous levels between L1 and S1

iv. Subjects with back and/or leg paint indicated for posterior stabilization with or without decompression at any level and posterolateral fusion

v. Unresponsive to conservative treatment for at least 6 months

vi. Radiographic evidence of primary diagnosis

b. Exclusion:

i. No healthy volunteers permitted

ii. More than two levels requiring posterolateral fusion (PLF)

iii. Spondylosis greater than Grade 1

iv. Prior failed fusion surgery at lumbar level(s)

v. Systemic or local infection in the disc or cervical spine, past or present

vi. Active systemic disease

vii. Osteoporosis, Osteomalacia, or other metabolic bone disease that would significantly inhibit bone healing

viii. Use of other bone graft, Bone Morphogenic Protein (BMP), or bone graft

substitutes in addition to or in place of those products specified

ix. BMI greater than 40

x. Use of post-operative spinal cord stimulator

xi. Known or suspected history of alcohol and/or drug abuse

xii. Involved in pending litigation or worker's compensation related to the spine

xiii. Pregnant or planning to become pregnant during the course of the study

xiv. Insulin-dependent diabetes mellitus

xv. Life expectancy less than duration of study

xvi. Any significant psychological disturbance that could impair consent process or ability to complete self-assessment questionnaires

xvii. Undergoing chemotherapy or radiation treatment, or chronic use of oral or injected steroids or prolonged use of non-steroidal anti-inflammatory drugs

xviii. Known history of hypersensitivity or anaphylactic reaction to dimethyl sulfoxide (DMSO).

772. All 3 clinical trials were "Terminated" before any results were produced.

773. Alphatec and Parcell saw this limited approval for clinical trials as an opportunity to market PureGen without premarket approval, 510K clearance, an exception to the Food Drug and Cosmetic Act, meeting the humanitarian device exception, investigational new drug (IND) application, or other permission to market PureGen, all in violation of the Food Drug and Cosmetic Act.

774. Alphatec and Parcell began a course of conduct designed to expand the application of PureGen by end users in excess of the approved clinical trial of PureGen. This course of conduct utilized fraud, false statements, material misrepresentation, and

deceit in order to broaden the sales of PureGen beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

775. The Food and Drug Administration (FDA) conducted an inspection of Parcell Laboratories between February 9-14, 2011.

776. After the inspection, the FDA responded quickly to the unlicensed marketing of the device PureGen by warning that PureGen was not the subject of an IND application nor a valid biologics license with a letter dated June 23, 2011.

777. The letter stated that the cells used in the production of PureGen were human cells, tissues, or cellular and tissue-based products (HCT/Ps) as defined in 21 CFR 1271.3(d).

778. Based on this analysis, the FDA determined that PureGen was a drug and biological product as defined in the Federal Food, Drug and Cosmetic Act.

779. According to the Public Health Service Act, a valid biologics license is also required to introduce a biologics device to the market.

780. Alphatec Spine did not acquire a valid biologics license to enter a biologics product into interstate commerce, in violation of 21 U.S.C. 355(a); 42 U.S.C. 262(a).

781. The FDA stated that PureGen, "does not meet all of the criteria in 21 CFR 1271.10(a) and therefore is not regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR Part 1271. Specifically, the product does not meet the criterion in 21 CFR 1271.10(a)(4)(ii)(b) because the product is dependent on the metabolic activity of living cells for its primary function."

782. As a result, a valid biologics license was required, which was never obtained by Alphatec or Parcell labs in regard to PureGen. Defendants knew all this.

783. Given this lack of a valid biologics license, the FDA determined that the marketing of PureGen violated both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.

784. In a statement to the press approximately a week after receiving the FDA Letter, Alphatec President Dirk Kuyper stated, "Both Alphatec Spine and Parcell Laboratories are fully committed to work closely and collaboratively with the FDA to address the questions related to the PureGen Product. We look forward to discussing the PureGen product with the FDA and sharing our clinical outcomes to date." See article "Alphatec comments on FDA's letter regarding PureGen product for spinal fusion procedures", Spinal News International, July 28, 2011, attached as Exhibit E.

785. No such cooperation by Alphatec and Parcell labs occurred and no clinical outcomes were shared with the FDA as all clinical trials of PureGen were "Terminated" and no data was released as to the findings.

786. In fact, Alphatec and Parcell responded to this letter by continuing to market PureGen in an unlicensed manner until Alphatec finally acknowledged the letter in or around February 2013, almost two years after receiving the letter, by stating it disagrees with the FDA's classification of PureGen as anything other than a tissue product – despite the clinical trial approval listing PureGen as "Biological: PureGen Osteoprogenitor Cell Allograft".

787. Furthermore, according to sales representative, Thomas Blank, Alphatec falsely informed distributors of PureGen that they "resolved" the issues addressed in the FDA letter, did not have to take PureGen off the market and it was "ok" for their distributors to continue marketing and selling PureGen.

788. Despite the approval for the clinical trial of PureGen which limited enrollment to 50 patients, Alphatec advertised in its 2012 Annual Report that PureGen had been implanted in over 3,500 patients.

789. PureGen further stated that it had been placed in these 3,500 patients with "no adverse events related to the product", despite no study, statistics or information to back up such a claim.

790. This 2012 annual report also identified PureGen as a biologic.

791. In the First Quarter of 2011, Alphatec Spine attributed part of its 40.9% increase in revenue to the PureGen product. See Becker's Spine Review, Alphatec Spine Reports $49.7M in Q1 Revenue, 40.9% Increase, May 5, 2011, attached as exhibit H.

792. Eventually, after PureGen had been unlawfully implanted in thousands of patients, Alphatec and Parcell conceded that PureGen is a tissue product and a biologic and stopped shipping PureGen in February of 2013.

PUREGEN AND OHIO LAW

793. It is the position of the Deters Law Firm that the distribution and use of PureGen by Dr. Durrani, Evolution Medical, Alphatec Spine, Inc., and West Chester/UC Health by Defendants is in violation not only of Federal Law as outlined in the FDA's letter, but Ohio State Law as well.

794. Ohio Revised Code 3715.65(A) states that "No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under section 505 of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040 (1938), 21 U.S.C.A. 301". Defendants violated this provision.

795. A “New Drug” is defined as “Any drug the composition of which is not generally recognized among experts by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof.” Ohio Revised Code 3715.01(9)(a).

796. PureGen’s status as a Biologic further supports the classification of a drug under the FDA and Ohio Law: “A "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service Act Sec. 351(i)). Additional interpretation of the statutory language is found in 21 CFR 600.3. Biological products also meet the definition of either a drug or device under Sections 201(g) and (h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).” See http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.

797. It is the position of the Deters Law Firm that PureGen is a drug as defined in ORC 3715.01 and that its distribution before FDA approval was in violation of ORC 3715.65(A). The Defendants with full knowledge and intent violated this statute.

PUREGEN AT THE HOSPITALS

798. On October 10, 2011, UC Health began purchasing PureGen from Alphatec. Thomas Blank was an employee of Innovative Medical Consultants, LLC and a sales representative, seller, marketer, and distributer of PureGen for the Northern Kentucky/Cincinnati area.

799. In his professional capacity, Thomas Blank was present during most, if not all, of the surgeries at issue where PureGen was secretly implanted into various Plaintiffs without informed consent or permission.

800. Thomas Blank worked directly with Alphatec Spine, Inc. and Defendants in the marketing and distribution of PureGen.

801. Additionally, Thomas Blank is a shareholder in Alphatec Spine, Inc.

802. On May 10, 2012 Evolution Medical, LLC, a physician owned distributorship (POD), owned in part (at least 40%) by Dr. Durrani and incorporated in Delaware, received a Kentucky Certificate of Authority.

803. Around this time, Thomas Blank began to work with Evolution Medical in the marketing and distribution of PureGen, in addition to his dealing with Alphatec Spine, Inc.

804. On July 20, 2012, UC Health with the full knowledge and consent of Defendants began purchasing PureGen from Evolution Medical, LLC.

805. The purchase of PureGen, the logistics of the billing, the bills of lading, the receiving and handling of PureGen for West Chester Hospital was handled by UC Health Purchasing.

806. The Defendants tracked West Chester/UC Health's purchases of PureGen from Evolution medical.

807. Specifically, Thomas Blank would provide the materials from Alphatec related to the use and approval of PureGen to Dwayne Brown on behalf of UC Health, who would request PureGen based on the amounts requested by Dr. Durrani and other doctors who used the product.

808. After the UC Health reps approved the use of PureGen, Thomas Blank and his associate Toby Wilcox would order the product, typically in bulk, and draft the requisite billing documents.

809. The PureGen ordered would be stored on site at WCH in the freezer of the operating rooms.

810. In addition to Dr. Durrani, other doctors at WCH used PureGen, including Dr. Chunduri, Dr. Curt and Dr. Shanti.

811. Defendants would purchase and allow these doctors to use a substance not approved by the FDA in patients without their informed consent.

812. Though WCH and UC Health do have patients fill out "informed consent" forms, no mention of PureGen or its non-FDA approved status is mentioned on these forms.

DR. DURRANI AND PUREGEN

813. In one of the few depositions taken of Dr. Durrani before his flight from the country he stated that PureGen is "essentially stem cells" and that he "used to use [PureGen] for a certain amount of time." Deposition of Dr. Durrani in *Brenda Shell v. Durrani*, p. 25-26, attached as Exhibit N.

814. This "certain amount of time" was approximately 3 years between 2010 and 2013, all while PureGen remained unapproved by the FDA.

815. Though downplaying his involvement with PureGen, Dr. Durrani, through his illegal POD Evolution Medical, distributed PureGen to West Chester/UC Health with the full knowledge and consent of Defendants.

816. Dr. Durrani and his Evolution Medical co-owner Toby Wilcox and Defendants, knew the Department of Health and Human Services and the United States Senate

Finance Committee has released reports on dangers of Physician-owned entities, notably Physician-owned Distributorships (POD's).

817. Dr. Durrani and Toby Wilcox's actions through Evolution Medical violated the Anti-Kickback Statute 42 U.S.C. 1320 and Stark Law 42 U.S.C. 1395.

818. Compliance with the Anti-Kickback Statutes is a condition of receiving payment from a Federally-funded healthcare program, and most private insurers have a parallel conditional requirement.

819. The Anti-Kickback Statute prohibits the payment and receipt of kickbacks in return for either procuring or recommending the procurement of a good, facility, or item to be paid in whole or in part by a federal healthcare program. 42 U.S.C. 1320a-7b(b).

820. In violation of 45 C.F.R. 46, and in furtherance of the scheme to feign avoidance of the anti-kickback statutes, Dr. Durrani, CAST, Alphatec and the Defendants experimented on patients by using PureGen in unapproved manners, without the informed consent of the patients, and subsequently billing their health insurance companies all while concealing the true nature of their actions.

821. Dr. Durrani also had connections with Alphatec as his personal calendar indicates meetings with Dirk Kuyper, President and CEO of Alphatec in 2008.

822. Dr. Durrani experimentally used PureGen bone graft in twenty cervical surgeries, along with as many as 72 thoracic, cervical, and lumbar surgeries, ignoring the limited uses it was approved for in the clinical trials.

823. Dr. Durrani, through his POD Evolution Medical, was essentially "double dipping" in his dealings with PureGen.

824. Dr. Durrani would sell WCH and the other hospitals the PureGen through Evolution Medical and then use and bill for the PureGen in his surgeries.

825. Dr. Durrani and Defendants knew such an arrangement was either unethical and illegal (though still not disclosing the use of PureGen) by having the patients sign an Acknowledgement of Potential Conflict of Interest form.

826. WCH and Defendant also benefited from this arrangement by up charging patients for the PureGen after purchasing it from Evolution Medical and Dr. Durrani.

827. At all times relevant, Dr. Durrani and Defendants was in exclusive control of the amount and ratio of PureGen bone graft that was experimentally implanted into patients.

828. PureGen was and remains unapproved by the FDA for use in humans without an Investigation New Drug ("IND") or experimental informed consent of the patient.

829. Dr. Durrani and Defendants did not receive experimental informed consent from patients, nor did he verify that an IND was obtained.

830. The basic “Informed Consent Forms” Dr. Durrani and CAST did have patients fill out made no mention of PureGen or the fact a non-FDA approved product was being implanted in their body.

831. In fact, Dr. Durrani and Defendants would even conceal the use of PureGen by intentionally withholding it from the billing records, noting on one Pre-Op Code sheet “Do Not Bill” twice in regard to PureGen.

832. Implanting PureGen in any part of the spinal canal without FDA clearance, proper trials, and patient consent is reckless battery and violates the Hippocratic Oath’s statement “I will prescribe regimens for the good of my patients according to my ability and my judgment and never **do harm** to anyone.” It is criminal.

833. A majority of the surgeries occurred AFTER the FDA inspection and subsequent warning on the non-FDA approved status of PureGen.

834. Following the cervical surgeries in which PureGen was implanted, the patients' pain became far worse and more extreme.

835. The patients attest to difficulty with swallowing unthickened liquid, medications in pill form, routine saliva, and food.

836. Many patients describe a choking sensation felt on a daily basis when swallowing and changes to the tone and audibility of their voice, along with a chronic cough.

837. Following the thoracic and lumbar surgeries, patients attest to increased spinal pain, difficulty with ambulation, numbness and tingling in lower extremities, decreased flexibility.

IV. CAUSES OF ACTION.

DR. DURRANI COUNTS:

COUNT I: NEGLIGENCE

838. Defendant Dr. Durrani owed his patient, Plaintiff, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

839. Defendant Dr. Durrani breached his duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, and improper follow-up care addressing a patient's concerns.

840. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendant Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: BATTERY

841. Dr. Durrani committed battery against Plaintiff by performing a surgery that was unnecessary, contraindicated for Plaintiff's medical condition, and for which he did not properly obtain informed consent, inter alia, by using BMP-2 and/or Baxano in ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiff.

842. Plaintiff would not have agreed to the surgery if they knew the surgery was unnecessary, not approved by the FDA, and not indicated.

843. As a direct and proximate result of the aforementioned battery by Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT III: LACK OF INFORMED CONSENT

844. The informed consent forms from Dr. Durrani which he required Plaintiff to sign failed to fully cover all the information necessary and required for the procedures and surgical procedures performed by Dr. Durrani. Dr. Durrani required an informed consent release.

845. In addition, no one verbally informed Plaintiff of the information and risks required for informed consent at the time of or before Plaintiff's surgery.

846. Dr. Durrani failed to inform Plaintiff of material risks and dangers inherent or potentially involved with her surgery and procedures.

847. Had Plaintiff been appropriately informed of the need or lack of need for surgery and other procedures and the risks of the procedures, Plaintiff would not have undergone the surgery or procedures.

848. As a direct and proximate result of the lack of informed consent, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT IV: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

849. Dr. Durrani's conduct as described above was intentional and reckless.

850. It is outrageous and offends against the generally accepted standards of morality.

851. It was the proximate and actual cause of Plaintiff's psychological injuries, emotional injuries, mental anguish, suffering, and distress.

852. Plaintiff suffered severe distress and anguish so serious and of a nature that no reasonable man or woman would be expected to endure.

COUNT V: FRAUD

853. Dr. Durrani made material, false representations to Plaintiff and their insurance company related to Plaintiff's treatment including: stating the surgery was necessary, that Dr. Durrani "could fix" Plaintiff, that more conservative treatment was unnecessary and futile, that the surgery would be simple or was "no big deal", that Plaintiff would be walking normally within days after each surgery, that the procedures were medically necessary and accurately reported on the billing to the insurance company, that the surgery was successful, and that Plaintiff was medically stable and ready to be discharged.

854. Dr. Durrani also concealed the potential use of Infuse/BMP-2 in Plaintiff's surgery, as well as other information, when he had a duty to disclose to Plaintiff his planned use of the same.

855. These misrepresentations and/or concealments were material to Plaintiff because they directly induced Plaintiff to undergo her surgery.

856. Dr. Durrani knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness as to their truth that knowledge of their falsity may be inferred.

857. Dr. Durrani made the misrepresentations before, during and after the surgery with the intent of misleading Plaintiff and their insurance company into relying upon them. Specifically, the misrepresentations were made to induce payment by the insurance company, without which Dr. Durrani would not have performed the surgery, and to induce Plaintiff to undergo the surgery without regard to medical necessity and only for the purpose of receiving payment.

858. The misrepresentations and/or concealments were made during Plaintiff's office visits at Dr. Durrani's CAST offices.

859. Plaintiff was justified in their reliance on the misrepresentations because a patient has a right to trust their doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.

860. As a direct and proximate result of the aforementioned fraud, Plaintiff did undergo surgery which was paid for in whole or in part by their insurance company, and suffered all damages as requested in the Prayer for Relief.

COUNT VI: SPOLIATION OF EVIDENCE

861. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.

862. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

863. Dr. Durrani's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

CAST COUNTS:

COUNT I: VICARIOUS LIABILITY

864. At all times relevant, Defendant Dr. Durrani was an agent, and/or employee of CAST.

865. Dr. Durrani is in fact, the owner of CAST.

866. Defendant Dr. Durrani was performing within the scope of his employment with CAST during the care and treatment of Plaintiff.

867. Defendant CAST is responsible for harm caused by acts of its employees for conduct that was within the scope of employment under the theory of respondeat superior.

868. Defendant CAST is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

869. As a direct and proximate result of Defendant CAST's acts and omissions, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: NEGLIGENT HIRING, RETENTION, AND SUPERVISION

870. CAST provided Dr. Durrani, inter alia, financial support, control, medical facilities, billing and insurance payment support, staff support, medicines, and tangible items for use on patients.

871. CAST and Dr. Durrani participated in experiments using BMP-2 and/or PureGen bone graft on patients, including Plaintiff, without obtaining proper informed consent thereby causing harm to Plaintiff.

872. CAST breached its duty to Plaintiff, inter alia, by not supervising or controlling the actions of Dr. Durrani and the doctors, nurses, staff, and those with privileges, during the medical treatment of Plaintiff at CAST.

873. The Safe Medical Device Act required entities such as CAST to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

874. Such disregard for and violations of federal law represents strong evidence that CAST negligently hired, retained, and supervised Dr. Durrani.

875. As a direct and proximate result of the acts and omissions herein described, including but not limited to failure to properly supervise medical treatment by Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT III: FRAUD

876. CAST sent out billing to Plaintiff's insurance company after the surgeries at WCH/UC Health.

877. The exact dates these medical bills were sent out are reflected in those medical bills.

878. These bills constituted affirmative representations by CAST that the charges related to Plaintiff's surgeries were medically appropriate and properly documented.

879. The bills were sent with the knowledge of CAST that in fact Plaintiff's surgeries were not appropriately billed and documented and that the services rendered at West Chester Hospital/UC Health associated with Dr. Durrani were not appropriate.

880. The bills sent by CAST to Plaintiff falsely represented that Plaintiff's surgeries were appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

881. Plaintiff relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiff for CAST's services in association with Dr. Durrani's surgery.

882. As a direct and proximate result of this reliance on the billing of CAST, Plaintiff incurred medical bills that she otherwise would not have incurred.

883. CAST also either concealed from Plaintiff that they knew about Dr. Durrani, including that Infuse/BMP-2 and/or PureGen would be used in Plaintiff's surgeries, or misrepresented to Plaintiff the nature of the surgeries, and the particular risks that were involved therein.

884. CAST's concealments and misrepresentations regarding Infuse/BMP-2 and/or PureGen and the nature and risks of Plaintiff's surgeries were material facts.

885. Because of its superior position and professional role as a medical service provider, CAST had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

886. CAST intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgeries, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiff at WCH/UC Health.

887. Plaintiff was unaware that BMP-2 and/or PureGen would be used in Plaintiff's surgeries and therefore, was unaware of the health risks of Infuse/BMP-2 and/or PureGen's use in Plaintiff's spine.

888. Had Plaintiff known before Plaintiff's surgeries that Infuse/BMP-2 and/or PureGen would be used in Plaintiff's spine and informed of the specific, harmful risks flowing therefrom, Plaintiff would not have undergone the surgery with Dr. Durrani at West Chester Hospital/UC Health.

889. Upon information and belief, Plaintiff believes the bills requested by Plaintiff will indicate that CAST falsely represented that Plaintiff's surgery was appropriately indicated, performed, and medically necessary in contra-indication of the standard of care.

890. Plaintiff is still awaiting ITEMIZED billing from CAST reflecting the exact totals charged for the use of BMP-2 on Plaintiff.

891. As a direct and proximate result of the fraud against plaintiff by CAST, Plaintiff sustained all damages requested in the prayer for relief.

COUNT IV: OHIO CONSUMER SALES PROTECTION ACT

892. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

893. CAST's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

894. CAST omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

895. CAST's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

896. CAST was fully aware of its actions.

897. CAST was fully aware that Plaintiffs were induced by and relied upon CAST's representations at the time CAST was engaged by Plaintiffs.

898. Had Plaintiffs been aware that CAST's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

899. CAST**,** through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

900. CAST's actions were not the result of any bona fide errors.

901. As a result of CAST's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid
b. Severe aggravation and inconveniences
c. Under O.R.C. 1345.01 Plaintiffs are entitled to:
    i. An order requiring that CAST restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiffs;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

V. PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests and seeks justice in the form and procedure of a jury, verdict and judgment against Defendants on all claims for the following damages:

1. Past medical bills;
2. Future medical bills;
3. Lost income and benefits;
4. Lost future income and benefits;
5. Loss of ability to earn income;
6. Past pain and suffering;
7. Future pain and suffering;
8. Plaintiff seeks a finding that their injuries are catastrophic under Ohio Rev. Code §2315.18;
9. Plaintiff seeks all relief available under the Ohio Products Liability Act R.C. § 2307.71-2307.80 and applicable law;
10. All incidental costs and expenses incurred as a result of their injuries;
11. The damages to their credit as a result of their injuries;
12. Punitive damages;
13. Costs;
14. Attorneys' fees;
15. Interest;
16. All property loss;

17. All other relief to which they are entitled including O.R.C. 1345.01

Based upon 1-17 itemization of damages, the damages sought exceed the minimum jurisdictional amount of this Court and Plaintiff seeks in excess of $75,000.

Respectfully Submitted,

/s/ Benjamin Maraan II
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JURY DEMAND

Plaintiffs make a demand for a jury under all claims.

/s/ Benjamin Maraan II
Benjamin M. Maraan II, (#0053661)